

**CMS-1501-P-499 Changes to the Hospital Outpatient Prospective Payment System
and Calendar Year 2006 Payment Rates**

Submitter : Mr. James Hugh

Date & Time: 09/16/2005

Organization : AMAC

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-499-Attach-1.DOC

CMS Administrator
Mark B. McClellan, M.D., Ph.D.
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1501-P
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Dr. McClellan:

American Medical Accounting & Consulting (AMAC®) is a 23 year old consulting and billing company working with over 800 hospitals, universities, freestanding centers, clinics and physician groups only in oncology.

We understand the amount of time and effort that CMS has made in understanding the costs associated with treatment delivery as is evidenced by the reasonable decisions to improve the reimbursement for hospitals in the specialty of radiation therapy. The technology advancements allow for more effective treatments for patients resulting in a savings to CMS in the long term. We would respectfully like to comment on the following:

"Therefore, we are proposing to discontinue HCPCS codes G0242 and G0338 for the reporting of charges for SRS planning under the OPPS, and to instruct hospitals to bill charges for SRS planning using all of the available CPT codes that most accurately reflect the services provided".

Comment:

We fully agree with CMS that the HCPCS temporary codes, G0242 - Cobalt 60-based Stereotactic radiosurgery planning and G0338 - planning for linear accelerator-based stereotactic Radiosurgery should be deleted and the normal CPT codes in radiation oncology utilized. This will enable all providers to use the appropriate codes that will reflect and reimburse for simple and more complex cases in the same way we have done since 1992 until the inception of the "old" G codes.

We also want to keep the current treatment delivery codes utilized in Stereotactic radiosurgery (SRS single session) and Stereotactic radiotherapy (SRT multi-session), G0243, G0173, G0251, G0339 and G0340.

A little note of historical information, since the 1980's the vernacular that has always been used by the societies and providers for Radiosurgery is the following, stereotactic radiosurgery (SRS) is a single session treatment and stereotactic radiotherapy (SRT) is a multi-session treatment.



Comment:

The large reduction of CPT code 57155 - Insertion of uterine tandems and/or vaginal ovoids for clinical brachytherapy, APC 192, from \$758.17 to a proposed \$255.66 is possibly an error. This 66% reduction will not reimburse the outpatient operative time, supplies and the staffing involved in this procedure. This procedure, prior to the low dose or high dose radioelement application, is usually performed in the out patient operative suite and then later transferred to the radiation oncology department.

Comment:

We would ask CMS to further analyze the reductions to 77761-77777 (APC 312) 77778 (APC 651) still does not take into account the work, time, operative room and staffing involved in these intracavitary and interstitial radioelement application procedures. As an example for 77778, the reduction of 43% will not cover the OR time for eye plaque procedures. It is possible that CMS has focused primarily on "prostate seed implants" and has not addressed the other body areas which are also treated with these procedures.

Comment:

77781 -77784 – High dose remote afterloading, APC 313, is scheduled for an approximate 4% decrease. This decrease, while small, does not address the increasing costs of maintenance, and staffing as required by the NRC for all these procedures.

Comment:

CPT code 77301 – IMRT planning, APC 310, has had a very consistent payment rate for the past few year at \$875 - \$813. This payment does not reflect the actual physics planning time and resources for this procedure. Most of the IMRT plans can take days to prepare and QA for the appropriate dose and outcome to the patient. We would like to propose to CMS to observe a typical head and neck case and the time spent by the dosimetrists, physicists and physicians in the planning stages of IMRT.

Comment:

CPT 77370 "Special Medical Radiation Physics Consultation", APC 304, was reduced last year by over 50% and no rationale was given as to this sharp decrease. This procedure code is the extra effort and reporting to the physician by the physicist in "special procedures" such as Stereotactic Radiosurgery, total body treatments, IMRT, and brachytherapy. A treatment course could consist of two or more of the above procedures and the coordination of the dosimetry, planning, and reporting to the physician of the complex nature of combining these procedures. In many instances such as total body treatments there is significant time spent by the physics department in developing treatment planning, immobilization and proper beam placement for these "special" patients. We would like CMS to observe the amount of time spent by the physicists and dosimetrists in collaborating with the physician in these special circumstances.

"We believe that consideration by the CPT Editorial Panel may facilitate appropriate dissemination of the new technology services across delivery settings and may bring to light other needed coding changes or clarifications. We are further proposing that a copy of the submitted CPT application be filed with us as part of the application for a New Technology APC assignment under the OPPS, along with CPT's letter acknowledging or accepting the coding application. We remind the public that we do not consider an application complete until all informational requirements are provided".

Comment:

We do not believe that CMS should adopt this method in the near future until all possible conflicts and "special interest" may be analyzed, discussed and resolved in using a new system with "outside interests". This new method might delay new technology procedures and devices longer than the current system is taking today and result in poor care to the patients. Any new methods of review that could affect delays in the treatment of cancer should be carefully thought out.

Thank you for your consideration in the above comments.

Sincerely,

James E. Hugh III, MHA, ROCC®
Senior Vice President

Submitter : Mr. EDWARD QUINLAN
Organization : Hospital Association of RI
Category : Health Care Professional or Association

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1501-P-500-Attach-1.DOC



The Hospital Association of Rhode Island
880 Butler Drive – Suite One
Providence, Rhode Island 02906
(401) 274-1838

Edward J. Quinlan
President

September 15, 2005

Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1427-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-1427-P, Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment Systems (OPPS) and Calendar Year 2006 Payment Rates; Proposed Rule.

Dear Dr. McClellan:

On behalf of our member hospitals, the Hospital Association of Rhode Island (HARI) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule establishing new policies and payment rates for hospital outpatient services for calendar year 2006.

We share the concern of the American Hospital Association (AHA) that many ambulatory payment classification (APC) rates continue to fluctuate dramatically, with payments much lower or higher in 2006 than in 2005. We agree that these changes make it extremely difficult for hospitals to plan and budget from year to year. Several of the evaluation and management (E/M) services APCs, especially clinic visits, continue to experience declines in payment rates.

Compounding this problem is the fact that the entire OPPS is underfunded, paying only 87 cents for every dollar of hospital outpatient care provided to Medicare beneficiaries. Hospitals must have adequate funds to address critical issues including but not limited to severe worker shortages, skyrocketing liability premiums, expensive drugs and technologies, aging facilities, and expensive regulatory mandates.

The proposed rule contains a number of significant policy changes, including changes to payments for handling costs hospital incur for separately paid drugs, increases in the threshold for the outlier policy, reduced payments for multiple imaging procedures, and changes to payment for rural hospitals.

Pharmacy Overhead and Drug Handling Payment Rate Adjustment

The proposed rule adjusts the APC rates for separately payable drugs to take into account pharmacy overhead and drug handling costs. Since CMS does not have separate hospital charge data on these pharmacy costs, in 2006 the agency proposes to pay 2 percent of the average sales price (ASP) for these products. For future payment rates, CMS proposes three distinct temporary HCPCS codes (C-codes) and

corresponding APCs to differentiate by level of overhead costs for drugs and biologicals. Hospitals would be instructed to charge the appropriate pharmacy overhead C-code when they provide separately payable drugs. We agree with AHA that handling costs for drugs and biologicals delivered in the hospital outpatient department are significant and should be reimbursed by Medicare. We, too, are concerned that the adjustment is not adequate for certain drugs having high handling costs due to special equipment or procedures due to the drugs' individual properties and agree that those drugs' payments be frozen. In addition, the requirement that hospitals establish separate charges for pharmacy overhead using the three proposed C-codes provides for potential confusion and error. Most importantly, Medicare providers must have uniform charges for all payers, but payers other than Medicare do not use the C-codes. If implemented, this policy would require hospitals to break the law by having two charges for their drugs. We therefore strongly oppose this proposal to require hospitals to establish separate charges for pharmacy overhead for separately payable drugs using the three proposed C-codes and join AHA in recommending that CMS work with stakeholder groups to collect further data and develop alternative and simpler solutions.

Outlier Policy - the proposed rule would decrease the set aside for outlier payments from 2 to 1 percent and increase the dollar threshold for receiving outlier payments by \$400, to \$1,575. This proposed threshold is quite high and we, too, request clarification on how it was determined. The proposed rule does not include data on the actual outlier payments made in 2005 and prior years. It would be logical that in the final rule CMS publish data on actual outlier payments made in 2004 and prior years and that actual outlier payments for 2005 and later years be reported as soon as possible, so that there is an understandable basis for the change.

Reduced payment for multiple imaging procedures - The proposed reduced payment when multiple imaging services are provided on the same day, with full payment for the highest paid imaging service and a 50 percent reduction in payment for additional procedures from the same "family" of procedures performed in the same session does not seem to take into account actual hospital cost data. Rather, it seems the Medicare physician fee schedule practice expense data was used for determining the level of the discount. This provides no real evidence to justify the reduction in payment or to suggest that the 50 percent discount represents the right level of efficiencies obtained by hospitals. We therefore join with the AHA in opposing this policy without better justification and with more substantial, hospital-based data to support the policy. We would also request clarification for terms such as "the same session."

HARI appreciates the opportunity to submit these comments on the proposed rule. If you have any questions about these comments, please feel free to contact me or Pat Moran, vice president - finance, at (401) 946-7887.

Sincerely,



Edward J. Quinlan
President

Submitter : Mr. Russ Ranallo
Organization : Owensboro Medical Health System
Category : Hospital

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-501-Attach-1.DOC

September 16, 2005

The Honorable Mark B. McClellan M.D., Ph.D
Administrator
The Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-1500-P
P.O. Box 8011
Baltimore, MD 21244-1850

**Ref: [CMS-1501-P] Medicare Program; Proposed Changes to the Hospital
Outpatient Prospective Payment Systems and Calendar Year 2006 Rates.**

Dear Administrator McClellan:

The Owensboro Medical Health System (OMHS) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule, which establishes new policies and payment rates for hospital outpatient services for calendar year 2006. We are pleased by CMS' openness in soliciting comments on the numerous changes it proposes to this remarkably complex and difficult payment system.

Attached are our detailed comments regarding CMS's proposed changes. We hope that CMS will consider our recommendations and make the appropriate adjustments. Please feel free to contact me at (270) 688-2855 if you have any questions or if you require additional information.

Sincerely,

Russ Ranallo
Vice President, Financial Services

Wage Index

OMHS *continues* to be concerned with the impact of wage index on the APCs and the inclusion of devices and technologies and former pass-throughs into the base APC system. The pass-throughs have been incorporated into the base system but it is not apparent that any review concerning the labor and non-labor split of the APCs has been performed. Currently, 60% of the APC is wage index adjusted. We feel that in certain APCs that have high cost in technologies, implants and drugs this is too large of a labor percentage. Hospitals have roughly the same acquisition costs for these items yet the hospitals with higher wage indices are paid more for these APCs while the hospitals with lower indices are paid less.

Our internal data shows that our labor expenses on APCs that have high dollar devices included in the payment (For example APCs 0106, 0107, and 222) are far less than the 60% adjusted by Medicare. We are being punished with lower payments for devices because our wage index is below 1.0 while other hospitals are benefiting with higher payments if their wage index is greater than 1.0. This inequity could prohibit hospitals with lower wage indices from being able to offer more advance implants and devices.

We commented on this last year with CMS stating that they would review the split to ensure appropriateness. We have no evidence that any review has been completed. We are again asking that CMS review the labor and non-labor split to confirm that the 60% is still appropriate and equitable across all APCs. We believe that those hospitals with lower wage indices are being unfairly treated on APCs with high dollar devices included.

Wage Index (continued)

Again, OMHS is concerned with the lack of apparent impact of occupational mix on the wage index for FY 2006.

On July 23, 2002 Glenn Hackbarth, Chairman of the Medicare Payment Advisory Commission provided testimony to the Subcommittee on Health Committee on Ways and Means regarding adjusting Medicare payments for local market input prices.

According to the testimony the objective of the occupational mix adjustment “is to account for differences beyond the control of the provider – local market prices – and not for the differences created by management decisions – the mix of labor. Thus, using aggregate wages and hours may distort the wage index by elevating the average wage per hour in markets where providers employ a costly mix of labor and depressing the average wage in markets where hospital employ a relatively inexpensive labor mix. These inaccuracies in the wage index may have substantial effects on payment accuracy.”

CMS has only included a 10% occupational mix impact in the proposed FY 2006 Blended Wage Index. We disagree with this position. By not factoring in the occupational mix

adjustment at a higher percentage, the problems and inequity that reside in the wage index continue to exist. Those providers that have employed a cheaper occupation mix should no longer continue to be punished through lower payments while those hospitals that employ a more expensive mix are rewarded for their inefficiency.

We agree with the judgment in the Bellevue Hospital Center v. Leavitt case that the relevant sentence of the statute is mandatory and that Congress did not give the Secretary the authority to implement the occupational mix adjustment beginning October 1, 2004 other than in full.

We are requesting that CMS review the position and change the Blended wage index to include 100% of the average hourly wage adjusted for occupational mix. We believe that hospitals were provided with enough time and several opportunities to ensure that the data collection was accurate. CMS seems to be more concerned with not changing the status quo and impacting providers rather than fixing an inequity that many hospitals have suffered under for years. We ask for the higher percentage to help those providers negatively impacted by the inaccuracy.

Wage Index (continued)

We do not believe the current rules regarding wage reclassifications are equitable when applied to single-hospital CBSAs. While it is true that the hospital in a single-hospital CBSA receives its own unique index, CMS fails to realize that the rules allow other hospitals within the same region to access wage indices that are higher than what their own unique wage index would be.

For example, Owensboro Medical Health System (OMHS) is in a single-hospital CBSA (#36980) with a proposed wage index of .8806. The Medical Center of Bowling Green and Greenview Hospital reside in a CBSA (#14540) less than 50 miles away with a wage index of .8222. However, both hospitals are reclassified to the Nashville MSA with a wage index of .9757. These hospitals secure millions more in Medicare payments per year even though its wage rate is lower than OMHS.

We are in a situation where many hospitals in our region secure higher wage indices through sole community and rural referral status. While these hospitals pay lower wages than we do, they access much higher payments through these regulations. The single hospital MSA is put into a position where it is difficult to compete through no fault of its own.

We recommend that CMS allow single-hospital MSAs to pursue reclassifications to other areas where the index may be higher.

Non-Pass Throughs

We are submitting this comment to bring to your attention an error relating to the payment rates for the wound-healing products Apligraf (C1305) and Dermagraft (C9201).

These products have been paid in the hospital outpatient prospective payment system as specified covered outpatient drugs and should continue to be paid in 2006 similar to other such drugs. Patient access to these important products is jeopardized by the payment rates in the proposed rule. We respectfully request that the payment rates for Apligraf and Dermagraft be corrected in the final rule.

Apligraf and Dermagraft are unique living human tissue substitutes for the treatment of chronic ulcers. Randomized prospective clinical trials have demonstrated the efficacy of these products to accelerate and support healing of chronic diabetic foot ulcers (Apligraf and Dermagraft) and venous leg ulcers (Apligraf) preserving and improving the quality of life of thousands of diabetics and other elderly patients who suffer from chronic leg and foot ulcers. Many of these patients would have had to undergo limb amputations without the benefits of Apligraf and Dermagraft.

In the proposed Hospital Outpatient Rule for calendar year 2006 the Centers for Medicare and Medicaid Services proposed to pay specified covered outpatient drugs at average sales price (ASP) plus six percent for the acquisition cost of the drug. The rule proposes to pay a pharmacy overhead charge of an additional two percent which results in a total payment for specified covered outpatient drugs of ASP plus eight percent.

In 2002 both Apligraf and Dermagraft were paid as a biological under the pass through list. Following the enactment of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, both products have been paid for as sole-source biologicals in 2004 and in 2005 under the specified covered outpatient drug provision. Both products were included in the General Accountability Office (GAO) survey of acquisition costs for specified covered outpatient drugs dated June 30, 2005 (GAO-05-581R). The GAO report included the relevant ASP rates for each product.

However, in the proposed rule both Apligraf and Dermagraft would be incorrectly paid based on rates derived from claims data in stead of payment at ASP plus eight percent. Although the proposed rule is intended to provide reimbursement of ASP+8% for covered products, in the case of Apligraf and Dermagraft, the reimbursement rate is proposed to be 30% below the selling price of the product.

Accordingly, both products experienced a significant decrease in payment: Apligraf -- 2005 outpatient rate \$1,130.88; 2006 proposed outpatient rate \$766.84 and Dermagraft -- 2005 outpatient rate \$529.54; 2006 proposed outpatient rate \$368.32

There may have been some confusion in the proposed rule because the products are reimbursed in the physician's office under codes with different descriptors. In the physician office setting, Apligraf and Dermagraft have been paid based on the ASP + six percent methodology under J7340 (Metabolic active Dermal/Epidermal tissue) and J7342 (Metabolically active Dermal tissue) respectively.

We ask CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%.

Submitter : Mr. Edward Goodman
Organization : VHA Inc.
Category : Hospital

Date: 09/16/2005

Issue Areas/Comments

GENERAL

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"See Attachment"

CMS-1501-P-502-Attach-1.DOC



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September 16, 2005

Mark McClellan, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1501-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates)

Dear Administrator McClellan:

On behalf of VHA Inc., I appreciate this opportunity to comment on the proposed rule concerning the 2006 Hospital Outpatient Prospective Payment System ("HOPPS") rates that were published in the Federal Register on July 25, 2005 (the "Rule").¹ VHA is a national alliance of leading not-for-profit health care organizations that work together to improve the health of the communities they serve. VHA delivers industry leading supply chain management services and enables regional and national member networks to improve clinical and operational performance and to drive sustainable results. Based in Irving, Texas, VHA has 18 local offices serving more than 2,400 health care organizations across the United States. VHA is deeply committed to the health and safety of Medicare beneficiaries that rely upon access to lifesaving intravenous immune globulins (IVIG) in the hospital outpatient setting.

We desire to work with the Centers for Medicare & Medicaid Services (CMS) and Congress to assure that reimbursement in the HOPPS setting in 2006 is adequate to sustain beneficiary access to IVIG. VHA member hospitals represent approximately 20% of the nation's patient usage of IVIG. IVIG is a life saving treatment used to prevent infections in people with immune deficiencies and other serious conditions.

The most troubling aspect of the proposed rule, in our view, is the significant payment rate reduction that has been proposed for IVIG, as it is likely to dramatically encumber beneficiary access to this critical therapy. The proposed rates reflect a 51% reduction in the payment rate for lyophilized and a 30% decrease for liquid IVIG. The reduced rate may adversely affect patients who depend upon this therapy.

Current IVIG Access Limited in 2005 As a Result of Physician Office Reimbursement Reductions

Since January 1, 2005, VHA member hospitals have received numerous calls from patients, physicians, home health care companies and sites of care concerning treatment problems related to Medicare reimbursement for IVIG treatment. In order to obtain a fair and unbiased assessment of the current impact of changes in Medicare reimbursement since January 2005 on patients with primary immune deficiency diseases (PID) who are being treated with IVIG and who are Medicare patients, the Immune Deficiency Foundation (IDF) conducted an independent survey of a sample of this population.

¹

69 Fed. Reg. 50448.

The IDF study identified a subset of patients from two national surveys and ongoing web survey of new patients who reported Medicare coverage. 202 patients with primary immune deficiency diseases, who were currently on Medicare and IVIG users, were interviewed about their treatment experiences in the past 12 months. The survey finds that nearly two out of five (39%) PID patients on Medicare being treated with IVIG have experienced a wide variety of IVIG treatment problems -- most commonly changed locations for infusions (12%) and postponed infusions (16%), increased intervals between infusions (11%), received lower dosage (6%), switched to less preferred product (7%) and/or less tolerated product (4%). 3% reported having had to stop infusions. Of the 12% who changed site of infusion, 51% reported receiving their infusions in a doctor's office a year ago, as opposed to 9% now. At the same time, 17% reported receiving infusions in a hospital outpatient setting, and 49% do so now. This is consistent with figures that show a greater than 15% increase in VHA member hospitals' purchases of IVIG in 2005.

According to the survey, the health of 40% of patients experiencing problems getting IVIG in the past 12 months and 15% of all PID Medicare patients on IVIG has been negatively affected. The survey provides verbatim reports from patients experiencing these problems on the role of the new reimbursement standards in these problems and the nature of the adverse health effects they have suffered as a result.

The experience of Medicare patients at the time this survey was conducted (primarily May-July 2005) may have been muted by the efforts of hospitals, many physicians, and home health care companies to help patients cope with the initial impact of the reimbursement rules. VHA member hospitals have been receiving more Medicare patients since January.

The information is consistent with the May-June 2005 IDF national survey of 287 physicians treating patients using IVIG, totaling 4189 patients with a primary immune deficiency disease (PID), and 935 patients with other disorders. The survey found that 31% of physicians that treat PID patients with IVIG reported patients experiencing significant problems related to reimbursement of IVIG. Of this group, 43% reported adverse health effects on patients as a result of reimbursement. The impact on patients included: 21% switched to a different site of care, 22% postponed infusions, 13% switched brands, and 8% had the interval between infusions increased.

Prior to the implementation of the Medicare Modernization Act (MMA), according to IDF's surveys, 30% of primary immune deficient patients relied on hospital outpatient facilities to receive their IVIG. Since the implementation of the MMA, that number has reportedly increased due at least in part to the fact that health care providers reimbursed under Medicare Part B have had difficulty purchasing IVIG at Medicare's reimbursable rates. We are concerned that under the proposed rule, hospitals will be subject to a similar reimbursement formula, which will put them in the position of administering IVIG at a loss.

RECOMMENDATIONS

It is our belief that CMS has the authority and flexibility to address the reimbursement problems that will arise if the proposed HOPPS rates are implemented, as we are currently witnessing under Medicare Part B. Specifically, CMS has worked with the dialysis and chemotherapy communities in order to assure that reimbursement does affect patient access and care. We request that CMS use this same flexibility for Medicare beneficiaries reliant on IVIG.

For reasons discussed in detail below, VHA Inc. recommends that CMS take the following actions, with the recommendations listed in order of priority:

1. Establish the 2006 HOPPS rate for IVIG based on recommendations from The Lewin Group and others by putting in place a "proxy" add-on payment rate until more comprehensive data is available.
2. In the absence of a proxy add-on, CMS should apply the 15% dampening provision to the HOPPS IVIG payment methodology for determining the 2006 payment rate.
3. Enhance the representativeness of the payment rate for each IVIG product by establishing unique HCPCS codes for each product.
4. Properly classify IVIG as a biologic response modifier (BRM) and reimburse its administration in a high complexity category.
5. ASP calculation should not include prompt pay discounts and the lag time between reporting and calculating OPPS ASP should be equal with the lag time utilized in calculating the Part B payment rate.

I. Provide an Add-on Payment

We understand that The Lewin Group and others are studying the complex issue of IVIG reimbursement. The data these groups collect will demonstrate the actual, market-based pricing of IVIG, which is the price at which broadly based, national samples of hospitals are routinely able to procure it. These studies will identify, catalogue, and estimate the cost of the full range of services that are related to the provision of IVIG to ensure that reimbursement covers these costs as well as the prices providers actually pay for the therapy itself. These cost estimates will help policymakers better understand the issues related to supply, pricing policy, and payment. These studies will and do suggest the magnitude of an appropriate "add-on" payment for IVIG, as well as the relative distribution of costs across product acquisition, handling, and administration.

In the interim, beginning **January 1, 2006**, we urge the agency to adopt a short-term solution to ensure that hospitals are adequately reimbursed. Payment rates should not only encompass hospitals' acquisition costs, but also pharmacy services, storage, and handling costs. We request that CMS adopt a "proxy figure" that could serve as a reimbursement rate until more in-depth analyses are complete.

II. Implement a Dampening Provision in the Absence of an Add-On

Alternatively, CMS could apply a modified version of the "dampening provision" proposed in the 2003 rulemaking process as many products lost their pass-through status and were paid under the median cost methodology to lessen the impact of dramatic reductions in payment rates for IVIG. CMS stated that the dampening option "mitigate[s] the potential for underpayment" in cases where "costs show significant fluctuations."²

Like 2003, the shift in payment methodology proposed for 2006 would drastically reduce the payment rate for IVIG. For example, at present the payment rate for IVIG in the hospital outpatient setting is \$80.68. The proposed 2006 OPPS payment rate for liquid IVIG is \$56.71 and \$39.46 for lyophilized. Even accounting for the 2% for pharmacy overhead costs, the proposed rates represent reductions of 30%

² 68 Fed. Reg. 4798, 48003 (Aug. 12, 2003).

and 51% respectively. It is unreasonable to expect hospital outpatient clinics to be able to adjust to such a drastic reduction in payment without unintended consequences.

Consequently, we recommend that CMS adopt a dampening provision that will limit the reduction in payment rate for IVIG to 15% during the first year of the new payment methodology. This could be achieved by setting the add-on payment at a level equal to the dollar amount necessary to achieve a payment reduction of no more than 15%. In this way, CMS can keep payment rates more in line with actual hospital acquisition costs and continue to use the market-based ASP as a reimbursement benchmark in a manner that will optimize patient care and healthcare costs.

III. Classify IVIG as A Biologic Response Modifier (BRM)

IVIG has been proven to modify the course of several diseases for which there are no other viable therapeutic options. Unfortunately, however, administering IVIG to these patients is a complex undertaking, taking between three to eight hours, and requiring careful monitoring by trained professionals. In part, this relates to the role that IVIG serves as a **biological response modifier (BRM)** in these diseases. A BRM is defined by the National Library of Medicine as: "a treatment intended to stimulate or restore the ability of the immune system to fight infection and disease". **IVIG is a BRM because it enhances the defective components of immunity to fight and protect against infection and complications of infection.** As the administration of IVIG is complex, like other BRMs, the process of administering the product should be reimbursed using higher complexity codes. This will allow for the effective and most importantly safe administration of IVIG to patients dependent upon it.

In primary immune deficiencies and in other indications, IVIG modifies aberrant immune response to protect, maintain and restore normal physiology to prevent disease. As is commonplace with BRM therapy adverse events (AE) occur frequently, and the risk of severe AEs is real. For example, the FDA licensing studies of IVIG for patients with PID (for which all currently available IVIG products are licensed) include an occurrence of AEs in up to 72% of patients. There are also severe AEs, many of which are acute, including: thromboembolism, hypotension, seizures, aseptic meningitis syndrome, anaphylaxis, acute respiratory distress syndrome, and transfusion associated lung injury. All IVIG products also include a black box warning regarding acute renal failure. The proper diagnosis of acute AEs in the context of IVIG infusions requires expert supervision and skilled intervention. This is necessary to minimize the impact of the AEs to the patient receiving treatment and in some cases can be life saving.

Given the gravity and acuity of risks in administering IVIG, special precautions are required. These include careful monitoring of the entire infusion process which can be as short as three to four hours, but as long as eight hours. Expert nursing care by registered nurses skilled in the administration and risks of IVIG is essential. Physician and nurse assessment of a patient to determine suitability for the infusion is also necessary as certain comorbidities of the primary diagnoses can preclude or alter the administration of IVIG. Order review and aseptic preparation by a registered pharmacist is necessary to assure that the product has been ordered and prepared appropriately. The immediate availability of the physician to evaluate the patient at any point during the infusion for assessment of potential complications is also critical. Finally, preparedness for a number of interventions to manage common infusion-related complications, including adjustment of the infusion rate, supplementation with physiological fluids, and provision of analgesics, non-steroidal anti-inflammatories, bronchodilators, antihistamines, steroidal anti-inflammatories, or occasionally systemic sympathomimetics is also required. Clearly, the safe and effective prescription and administration of IVIG requires a coordinated effort by highly skilled professionals.

IV. Establish Unique HCPCS Codes for Each Brand of IVIG

To the extent that CMS finalizes its proposal to pay for all separately payable drugs under OPPS based on ASP information, we believe that CMS could enhance the representativeness of the payment rate for each IVIG product by establishing unique HCPCS codes for each product. That would allow CMS to determine an ASP for each product based on its own ASP information, yielding rates that are pertinent to each product and thus may enhance access to IVIG products.

It is important to understand that all eight licensed IVIG products in the United States are not the same and that the manufacturers' processes have a significant impact on patient care. IVIG therapies are not generically interchangeable. Therapies differ in terms of donor pools, manufacturing and final formulation. Indeed, a number of these differences can, and do, affect individuals' tolerability, risk of adverse events, infusion rate, and potential efficacy. Hospitals routinely have more than one brand of IVIG product on their formulary of approved drugs.

Although this class of therapeutics may be equivalent in some aspect, the U.S. Food and Drug Administration (FDA) recognizes each IVIG brand as generically unique, and actually makes each drug go through individual clinical trial protocol to receive licensure, even if it is from the same manufacturer. This is because of the differences in basic fractionation and the addition of various modifications for further purification, stabilization and virus inactivation/removal that have yielded products clearly different from one to another. In addition, there are well-established differences in chemical structure, antibody content, subclass distribution and electrophoretic profile. Clearly, the composition of the final products differs widely.

IVIG therapy is prepared from plasma pooled from thousands of donors. Most production processes begin with sequential precipitation and fractionation with ethanol to isolate IgG from other plasma proteins. The IgG concentrates from initial fractionation are subjected to additional processing to produce material suitable for intravenous administration. This is where major differences exist among products and where biologic function is most susceptible to alteration.

Different product characteristics include the following:

- **Liquid vs. Lyophilized**

The manufacturing process influences whether the final product is in liquid or lyophilized (freeze-dried powder) form. In ready-to-use form, the liquid preparations shorten preparation time and delays for patients. However, lyophilized preparations may have a longer shelf life without the need of refrigeration and are often less costly.

- **Product Concentration**

The manufacturing process also affects product concentration. Products that can be given at higher concentrations decrease volume load, an important aspect in certain patient populations. Concentrating certain products by reconstitution in a smaller volume will increase the osmolality of the final solution and may contribute to significant adverse events such as renal complications or thromboembolic episodes. However, patients that can tolerate rapid infusions can receive higher concentrations of IgG, which would result in shorter infusion times.

- **Product Composition**

The variety of manufacturing processes, as well as starting materials, leads to differences among preparations that may be clinically important. Choosing the preparation of IVIG must take into account specific differences that can significantly affect outcome in recipients.

- **Fluid Volumes**

The ability to deliver higher amounts of IgG in lower volumes has a major impact on recipients who may be intolerant of large fluid volumes, such as infants or patients with congestive heart failure or renal insufficiency.

- **Sugar Content**

Various sugars, such as: sorbitol, glucose, and sucrose have been added to some preparations as a stabilizer and preservative in order to prevent aggregate formation. Some products contain no sugar. A major concern associated with sugar content is the incidence of significant adverse events, particularly acute renal failure or insufficiency. Although rare, the CDC reported that 90% of the IVIG-associated renal adverse events in the United States occurred with sucrose-containing IVIG preparations.

- **Sodium Content**

In IVIG solutions, the major contributors to osmolality include sodium, sugars, and other excipient proteins. Solutions of IVIG range from physiologic osmolality to solutions that far exceed these levels. Some sugar-stabilized products have higher osmolalities than other sugar stabilized and sugar-free preparations. In reconstituting lyophilized preparations, careful attention to osmolality is required as adverse events may occur with solutions exceeding the physiologic range. With some lyophilized preparations, reconstitution to higher concentrated solutions results in hyperosmolar solutions.

- **pH**

The pH optimum for IVIG to prevent aggregation is 4.0-4.5. Consequently, for preparations at higher pH, agents are added to maintain stability and prevent aggregation. There are various reports that low pH may be associated with phlebitis.

- **IgA Content**

Patients with selective IgA deficiency and the ability to produce antibodies may be at risk for developing IgE or IgG anti-IgA antibodies resulting in reactions, possibly anaphylaxis.

- **Antibody Titers**

There are marked differences in the levels of some antibodies among correctly licensed products, which could significantly determine efficacy of intervention with IVIG.

Patient experiences validate these differences. The IDF Treatment Experiences and Preferences of Patients with Primary Immune Deficiency Diseases survey of 2002 showed that patient reaction to IVIG demonstrates that this therapy is not a commodity. The majority of IVIG users surveyed thought there were either a lot (24%) or some (31%) difference between IVIG products in their tolerability. There was also a wide sense that some products may be more effective for specific individuals than others. Given the evidence highlighted above, it is clear that access to the complete range of products is necessary to ensure the physician's ability to provide optimal care.

V. Revise Aspects of the ASP Calculation

Currently, the ASP calculation includes both "prompt pay" and "cash discounts" that manufacturers offer to distributors of IVIG. The current ASP + 6% reimbursement in the Part B physician's office setting does not adequately cover the actual costs of acquiring and safely administering IVIG. The inclusion of prompt pay discounts in the formula for calculation of ASP could have the unintended consequence of reducing the actual manufacturer's average selling price of IVIG. We request that CMS consider this issue when formulating the final rule.

As mentioned above, the IVIG rates based on ASP+ 6%+ 2% for pharmacy overhead costs in the 2006 proposed rule raise concerns. The present reimbursement environment under Medicare Part B has lead to a situation where in certain cases health care providers can no longer provide IVIG because the acquisition cost of the therapy is exceeding its reimbursement. This has resulted in patients being shifted to the hospital outpatient site of service for treatment. With Medicare now proposing to implement the same model for the outpatient site of service, plus an additional 2% of ASP for hospital pharmacy overhead, we are concerned that a similar situation may develop in hospital outpatient care. As you are aware, the June 2005 Medicare Physician Advisory Commission report found that in the hospital outpatient system, hospital overhead is estimated to be 25-33% of ASP. Further, CMS' own Ambulatory Payment Code Advisory Committee recommended that CMS reconsider the 2% add-on for pharmacy overhead costs in addition to reviewing industry data regarding such costs. We, too, request that you consider this, specifically as it relates to IVIG, when formulating the final OPPTS rule.

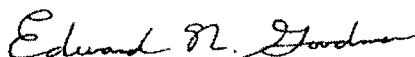
Furthermore, the nine-month lag time applied to HOPPS should at a minimum be balanced with the six-month lag time used in the Part B calculation. The six-month lag time applied to Part B is not ideal; however, the methodologies between the two sites of service should be equalized.

CONCLUSION

VHA Inc. appreciates the opportunity to comment on the HOPPS proposed rule. We are deeply concerned about the impact the rule could have on the lives of patients who rely upon IVIG. We do not believe that the drastic drop in the proposed reimbursement rates for this life sustaining therapy for beneficiaries is sound policy. We urge CMS to consider implementing an add-on for IVIG or, at a minimum, to apply a dampening mechanism that would mitigate reimbursement reductions to no greater than 15% of current rates.

We look forward to working with CMS and the Administrator toward that goal. Please contact William Woodward at (972) 581-5231 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,



Edward N. Goodman
Vice President, Public Policy

Submitter : Dr. Harvey Neiman
Organization : The American College of Radiology
Category : Health Care Provider/Association

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-503-Attach-1.DOC



September 16, 2005

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates

Dear Dr. McClellan:

The American College of Radiology (ACR), representing over 32,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, writes to provide comments on the "Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" published in the Federal Register on July 25, 2005 as a proposed rule with the comment period ending on September 16, 2005.

Our comments will address multiple diagnostic imaging procedures, proposed changes to packaged services, proposed use of single and multiple procedure claims, brachytherapy proposed payment policies, proton beam therapy, stereotactic radiosurgery, contrast-enhanced imaging procedures, computerized reconstruction, drug handling costs, device-dependent APCs, and magnetoencephalography (MEG).

Multiple Diagnostic Imaging Procedures

In this rule, CMS proposes to implement the MedPAC recommendation to "reduce the technical component payment for multiple imaging services performed on contiguous body parts." Specifically, CMS proposes to make full payment for the procedure with the highest APC payment rate and to make a 50% reduction in the OPPS payments for some second and subsequent imaging procedures performed in the same session.

The ACR agrees with the CMS position that, when some of the procedures identified by CMS are performed in the same session, some of the resource costs are not incurred twice. However,

the ACR has serious concerns that CMS has used external rather than internal data and methodology as the basis for this proposal. In using the Medicare Physician Fee Schedule (MPFS) methodology and data, rather than that of the HOPPS/APC process, CMS has ignored the fact that the cost efficiencies of performing multiple imaging procedures in the same session are already captured and accounted for in hospitals' annual cost reports to CMS and therefore already factored into the APC payment calculation. Therefore, the ACR recommends that CMS abandon the MPFS methodology and instead use data and methodology internal to the HOPPS/APC process in this analysis.

The HOPPS/APC process requires each hospital cost center to annually submit its aggregate charges and costs for the year to CMS. From this data, a cost/charge ratio is determined for each cost center. This cost/charge ratio is applied to charges for specific procedures to determine true costs and those costs are summed nationally to derive a median upon which the APC value is based. The ACR and its consultants believe there is ample evidence to indicate that the cost efficiencies in the technical component, which occurs when some imaging procedures are performed in the same session, is already accounted for when a hospital cost center submits its annual cost data.

Since the HOPPS/APC methodology already accounts for the cost efficiencies of multiple procedures in the same session, an additional 50% reduction, as described in this proposed rule, would contradict this methodology and systematically disadvantage hospitals relative to other imaging facilities. It would also result in an unintended, inappropriate and severe financial penalty to hospitals, making it difficult for them to upgrade equipment, hire necessary staff and provide the same hours of outpatient imaging operation, thus decreasing access of necessary care to Medicare beneficiaries.

- The ACR therefore supports the APC Advisory Panel's recommendation to delay this proposal for one year because further study is necessary; and, to consult with the ACR in this process.

Proposed Changes to Packaged Services

For CY2006, CMS is proposing to accept the APC Panel recommendation that CPT code 76937 (Ultrasound guidance for vascular access) remain packaged into the vascular access procedure codes. CMS is concerned that there may be unnecessary overuse of this procedure if it is separately payable. However, CPT has set specific coding and documentation guidelines of when this service should be billed. In addition, CMS believes that the service would always be provided with another separately payable procedure, so its costs would be appropriately bundled with the definitive vascular access service. However, it is the more difficult line placements that are referred to radiology that require image guidance. The ACR is concerned that these services and their costs will not be properly allocated to the radiology cost centers.

Therefore, the ACR disagrees with the APC Panel recommendation that CPT code 76937 remain packaged. Instead, we ask that CMS allow for separate payment.

Based on the original Institute of Medicine's report, "To Err Is Human: Building a Safer Health System," a recommendation was made by the Stanford Group to increase ultrasound guidance during CV line placement to decrease patient morbidity. It would seem that packaging will discourage the increased use in guidance for those difficult cases as it only adds non-reimbursable cost to the procedures.

In addition, the Agency for Healthcare Research and Quality (AHRQ) deemed the use of ultrasound to guide vascular access to be one of eleven most highly rated clinical practices to improve patient safety.¹ Also, it has been documented that 25% of injuries related to central vascular catheters could have been prevented with the use of ultrasound.² However, lack of payment for investment in equipment is cited in the AHRQ report to be a hurdle to adoption of this patient safety measure. Furthermore, lack of separate payment suppresses hospital cost reporting on claims. Although CMS allows for reporting of packaged services, because there is no payment on those packaged services, hospitals often do not report them. As a result, it is unlikely that the payment rates of the vascular access procedures reflect the added costs associated with providing ultrasound guidance.

- To ensure that Medicare beneficiaries have access to safe, high quality care, the ACR recommends that the Status Indicator assigned to CPT code +76937 be changed to an "S" allowing for separate payment of this service when provided in the hospital outpatient setting and that CPT code +76937 be assigned to APC 0268 - Ultrasound Guidance Procedures.

Proposed Use of Single and Multiple Procedure Claims

For CY 2006, CMS is proposing to continue to use single procedure claims to set the medians on which the APC relative payment weights would be based. CMS agrees that, optimally, it is desirable to use the data from as many claims as possible to recalibrate the APC relative payment weights, including those with multiple procedures. CMS is also proposing to continue using date of service matching as a tool for creation of "pseudo" single claims and to continue the use of a bypass list to create "pseudo" single claims.

- The ACR has continuously supported Medicare's policy to utilize as much hospital claims data as possible in order to calculate the APC weights. The ACR encourages CMS to continue to search for better ways to use and incorporate multiple-procedure claims data into the calculation of the weights for APCs. This is critical in the areas of interventional radiology and radiation oncology where submission of multiple-procedure claims is the norm rather than the exception. The ACR would also like to ensure that current APCs for codes on the "bypass" list are not devalued by lack of good data in order to provide single claims for others.

¹ AHRQ Evidence Report/Technology Assessment, No. 43 Making Health Care Safer: A Critical Analysis of Patient Safety Practices; 2001

² Anesthesiology 2004;100:1411-8. Injuries and Liability Related to Central Vascular Catheters. A Closed Claims Analysis.

Brachytherapy

All radiation oncology procedure codes (CPT codes 77xxx) have proposed increases in 2006 under HOPPS except brachytherapy codes in APCs 312, 313 and 651 which have proposed reductions (see Table 1).

The ACR believes that the proposed brachytherapy reductions are based on several factors, including: inaccurate hospital coding of brachytherapy source device “C” codes; elimination of multiple-procedure claims used to determine relative weights; and utilization of “incorrectly” coded brachytherapy claims to determine payment rates.

Table 1. Comparison of 2005 vs. Proposed 2006 HOPPS Payment Rates for Brachytherapy APCs

APC	CPT Codes	2005 Payment	2006 Proposed Payment	Percentage Change from 2005 to 2006
312 Radioelement Applications	77761, 77762, 77763, 77776, 77777	\$317.87	\$296.90	-6.6%
313 Brachytherapy	77781, 77782, 77783, 77784, 77779	\$790.75	\$763.48	-3.4%
651 Complex Interstitial Radiation Source Application	77778	\$1,248.93	\$720.71	-42.3%

- The ACR recommends the following: 1) use only “correctly coded” claims for brachytherapy APCs 312, 313 and 651; and 2) require mandatory hospital coding of appropriate brachytherapy source “C” codes for brachytherapy procedure APCs 312, 313 and 651.

Proposal to Move CPT 57155 from APC 193 to APC 192

CMS proposes to move CPT 57155 *Insertion of uterine tandems and/or vaginal ovoids for clinical brachytherapy* from APC 193 *Level V Female Reproductive Procedures* to APC 192 *Level IV Female Reproductive Procedures*. The current payment for CPT 57155 is \$758.17 and decreases by 66.4% in 2006 with assignment in APC 192 with a 2006 proposed payment of \$255.66. We note that some CPT codes were moved to different APCs without a discussion in the preamble providing the rationale for the changes. For example, there was no discussion in the proposed rule regarding the proposed assignment of CPT 57155 to APC 192 and we are concerned that a reduction of 66% could have a negative impact on Medicare beneficiaries’ access to this important treatment for vaginal and/or uterine cancer.

- The ACR recommends that CMS maintain CPT 57155 in APC 193 *Level V Female Reproductive Procedures*. Further, we request that all changes to APC assignments be discussed in the preamble for future proposed and final rulemaking.

Proton Beam Therapy

CMS is proposing to move CPT codes 77523 and 77525 from New Technology APC 1510 (\$850 for the CY 2005) to clinical APC 0667 (Level II Proton Beam Radiation Therapy) based on a median cost of \$934.46 for CY 2006.

- The ACR agrees with this CMS proposal.

Stereotactic Radiosurgery

CMS is seeking public comment on the clinical, administrative, or other concerns that could arise if CMS were to bundle Cobalt 60-based Stereotactic Radiosurgery (SRS) planning services, currently reported using HCPCS code G0242 and proposed for CY 2006 to be billed using the appropriate CPT codes for planning services, into the Cobalt 60-based SRS treatment service, currently reported under the OPPS using HCPCS code G0243.

- The ACR recommends the elimination of HCPCS codes G0242 (Cobalt 60-based planning) and G0338 (linac-based planning) and instead utilize existing CPT codes as determined by the process of care. SRS treatment planning is already well described by CPT codes (77295, 3D simulation or 77301, IMRT planning) and other simulation and physics codes (77300, 77370 and 77315) are currently used by physicians for their portion of the procedure.

Contrast-Enhanced Imaging Procedures

The ACR thanks CMS for its proposal to pay separately for low osmolar contrast material and most MR contrast agents. We are concerned, however, that the separate payment will not adequately compensate for the reduced payment which CMS proposes for APC 283, *CT with Contrast Material*, and APC 333, *CT and CT Angiography without followed by with Contrast*.

- The ACR does not understand why CMS is proposing to reduce payments for APCs 283 and 333 to a level that results in an overall net loss for contrast-enhanced CT studies. The ACR recommends that CMS allow the cost data to naturally adjust the CT payment rates to account for LOCM being paid separately similarly to how this method was used when CMS ruled that all LOCM was packaged.

Computerized Reconstruction

The ACR notes, with concern, a proposed reduction in payment for APC 417, *Computerized Reconstruction* of \$25. It was neither discussed in the preamble nor obvious in the 2006 data of why this decrease has occurred. Considering the possibility that computerized reconstruction may undergo significant changes in its coding structure which may result in recognition of the true complexity of these procedures and a subsequent marked reduction in their volume,

- The ACR recommends a one year delay in the implementation of the proposed reduction for APC 417 in order that the effect of changes in this technology be better reflected in its APC payment.

MedPAC Report on APC Payment Rate Adjustment of Specified Covered Outpatient Drugs

CMS proposes to pay for separately payable radiopharmaceutical agents based on their charges in the claims submitted by hospitals converted to costs. MedPAC found that the handling costs associated with radiopharmaceuticals were especially difficult to study given the variety of hospital outpatient settings in which these agents are used, the many different clinical uses for them, and significant differences in the agents themselves and in the methods for preparing them. As a result, handling costs for radiopharmaceuticals were found to vary a great deal due to differences in such factors as site of preparation, personnel time, shielding, transportation, equipment, waste disposal, and regulatory compliance requirements. However, as MedPAC also found that handling costs for drugs, biologicals, and radiopharmaceuticals were built into hospitals' charges for the products themselves. CMS believes that the charges from hospital claims converted to costs are representative of hospital acquisition costs for these agents, as well as their overhead costs. CMS is not proposing to create separate handling categories for radiopharmaceutical agents for CY 2006. However, CMS is proposing to collect ASP information for radiopharmaceuticals in CY 2006. CMS is seeking comments on appropriate categories for potentially capturing radiopharmaceutical handling costs.

- The ACR adheres to the APC Advisory Panel's recommendation that CMS delay for one year implementation of the proposed codes for drug handling cost categories so that further data and alternative solutions for making payments to hospitals for pharmacy overhead costs can be collected, analyzed by CMS, and presented to the Panel at the next meeting. The ACR would also like to be involved in this process.

Device-Dependent APCs

The ACR is concerned that CMS did not continue its policy of stabilizing all device-related APC rates by protecting against significant cuts to APCs. For the last several years, CMS established a "dampening" adjustment to virtually all APCs (except "New Technology" APCs). These adjustments were created to limit the impact of payment reductions from year to year.

In the 2006 proposed rule, CMS acknowledged that a payment reduction of more than 15% from the 2005 HOPPS payment rate might be problematic for hospitals that provide these services.

To address the lack of C-code data and the significant reductions for several APCs, CMS is proposing to adjust the median costs for the "device-dependent" APCs in Table 15 – "Proposed Median Cost Adjustments For Device-Dependent APCs For CY 2006" to 1) the higher of the 2006 unadjusted median or; 2) 85% of the adjusted median on which payment was based for 2005 HOPPS. The "device-dependent" adjustment factor proposed for 2006 was not applied to APC 651 for Complex Interstitial Brachytherapy.

- The ACR recommends that CMS apply the dampening adjustment to all device-related APCs, including APC 651, and limit the reduction in payment from 2005 to 2006 rates.

Other New Technology Services

CMS proposes to set magnetoencephalography (MEG) APC levels at \$674 for all CPTs in FY 2006 decreasing from FY 2005 \$5,250 (CPT 95965 - MEG, recording and analysis; spontaneous brain activity; \$950 (CPT 95966 - Evoked magnetic fields, single modality); and \$1,450 (CPT 95967 - Evoked magnetic fields, each additional modality).

- The ACR believes that the current values of reimbursement for MEG are at appropriate levels to reflect the actual costs. Similar to proton therapy, there are only a limited number of facilities that perform MEG. CMS' decision to change this payment rate for 2006 was based on a low volume of data and a wide range of charges. In addition, there does not appear to be any cost data for code 95967 possibly skewing the low recommended payment rate for 2006. Therefore, the ACR recommends delaying this proposal for one year in order for CMS to acquire additional data and reanalyze.

Conclusion

Thank you for the opportunity to comment on this proposed rule. The ACR looks forward to continued dialogues with CMS officials. Should you have any questions on the items addressed in this comment letter, or with respect to radiology and radiation oncology, please contact Carisia Switala at the ACR. Carisia may be reached at 1-800-227-5463 ext. 4587 or via email at CSwitala@acr.org.

Respectfully Submitted,



Harvey L. Neiman, MD, FACR
Executive Director

cc: Herb Kuhn, CMS
Ken Simon, MD, CMS
John A. Patti, MD, FACR, Chair, ACR Commission on Economics
James Rawson, MD, FACR, Chair, ACR Economics Committee on HOPPS/APC
Pamela J. Kassing, ACR
Maureen Spillman-Dennis, ACR

CMS-1501-P-504

Submitter : Mr. D Dorris
Organization : Jewish Hospital Healthcare Services
Category : Hospital

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-504-Attach-1.PDF



**Jewish Hospital
HealthCare Services**

Attachment #504
a century of excellence

100

September 16, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

**Re: Proposed Changes to the Hospital Outpatient Prospective Payment System (OPPS)
& Calendar Year 2006 Payment Rates**

The purpose of this correspondence is to submit Jewish Hospital Healthcare Services' (JHHS) comments and concerns regarding the proposed 2006 OPPS rule that was published in the Federal Register on July 25, 2005. JHHS is a not-for profit health system with a network that encompasses 60 facilities and 1200 inpatient beds. JHHS includes Jewish Hospital, a 442-bed regional referral center providing organ transplant and heart failure services. JHHS recognizes the huge responsibility and amount of work borne by CMS to refine OPPS both to implement statutory requirements as well as to improve the system based on continuing experience and access to better data. We appreciate the efforts of CMS and the opportunity to provide input on proposed changes before they are finalized into policy. Please find below our comments, concerns, and suggestions related to specific provisions listed in the 2006 proposed rule.

APC Relative Weights - Proposed Use of Single & Multiple Procedure Claims

JHHS supports the use of most recent claims and cost report data to set 2006 payment rates. We also support the expanded use multi-procedure claims, as we believe this practice will provide improved hospital cost estimates. However, when payment for a specific item or service drops precipitously and incongruently with easily demonstrable cost information, such as the case with ICD payments in 2006, we urge that CMS use supplemental external cost sources to make appropriate adjustments in payment levels.

Outlier Payments

Outlier payments are important to supplement APC payment levels to hospitals to help off-set hospital losses associated with high-cost cases. As a provider of many services involving new technology services with many involving high cost medical devices and drugs that may have payment rates that are, at least initially, inadequate to cover the costs of these services, we are concerned that decreasing the outlier may have a negative impact. The proposed rule contains no analyses that support its proposal to reduce the outlier pool and we recommend that no changes be made until such analyses are performed and made available as part of the proposed rule.

Business Office
P. O. Box 2587
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Hyperbaric Oxygen Therapy

Jewish Hospital, as a provider of hyperbaric oxygen services, is concerned that the CMS claims data does not accurately reflect the costs of this therapy because of potential hospital miscoding and use of hospital aggregate cost to charge ratios which do not reflect the accurate ratio for hyperbaric oxygen therapy. We ask that the HBO2 payment rate be increased on the basis of external data provided by the Hyperbaric Oxygen Therapy Association to the APC Advisory Panel.

Device Dependent APCs

As Jewish Hospital performs a large number of outpatient procedures involving a medical device, we are very concerned that CMS is relying on data submitted with C codes when those codes were not mandated for use in this time period (CY2004). In the proposed rule, the payment rates for procedures involving some devices were significantly decreased. As a health care provider of these services, these payment reductions are a serious concern. Specifically, changes should be made to the 2006 proposed payment rates for ICDs to be more closely aligned with the actual costs involved in providing these devices and services.

In the proposed rule, CMS recommends a decrease of 14.1% from last year's rate for ICD devices. Payment decreases of 14% from one year to the next are problematic on their face and can not be justified, particularly when the 2005 rates show a 2.3% reduction from the year before. No aspect of health care has dropped that much in two years. The resulting APC rates are lower than our institution's cost for the ICD device, leaving us with a loss for the device acquisition cost and no payment for our procedural costs. These losses make it very difficult for us to continue to offer device implant procedures in the outpatient hospital setting. To rectify this issue, we request that CMS calculate the 2006 payment rates for ICD implant procedures using 2005 payment rates plus the 3.2% hospital update. We understand that the August 2005 APC Advisory Panel has made the same recommendation to CMS. The resulting payment rates would be more in line with our facility's costs of performing these services.

For 2006, CMS is proposing to move the left ventricular lead implant associated with cardiac resynchronization pacing and defibrillation systems (CPT 33225) from APC 1525 to APC 0418. Although the payment rate for the implant would increase from \$3,750 to \$6,458 with the proposed change in APC, the move to the new APC actually equates to a lower rate of reimbursement overall than the procedure was paid in 2005 (\$3,229 v. \$3,750) as the status indicator would change from a status "S" meaning that it was always paid at 100% of the APC payment rate, to a status "T" which means that it is subject to a 50% reduction in multiple procedure scenarios. The assignment of status indicator "T" does not adequately compensate hospitals for additional procedural time and resources associated with this service. The implant procedure for the cardiac resynchronization pacing and defibrillator systems parallel that of a conventional dual chamber pacemaker or ICD with the exception of the implantation of a left ventricular lead and are therefore not duplicative.

Pass-Through Payments for Devices

JHHS supports the plans to modify the criterion regarding surgical implantation and to create a new device category for those instances where an existing device category does not appropriately describe the new type of device.

E/M Services

JHHS is disappointed that the 2006 rule does not propose national guidelines for evaluation and management services as the current lack of guidelines potentially puts hospitals at risk for lack of uniformity in coding as well as prevents CMS from being able to gather meaningful data that would assist in setting equitable and appropriate payment rates.

Proposed Payment for Observation Services

JHHS supports the planned changes as they will result in a simpler more reasonable process for providing necessary outpatient observation services.

Inpatient-Only Procedures

JHHS urges CMS to make policy modifications to allow for the procedure to be appealed and billed as an inpatient if the hospital is able to provide documentation as to the physician's intent, patient's clinical condition, and the circumstance that allowed the patient to be safely sent home with an admission. Inasmuch as physicians, not hospitals, determine where procedures can be safely performed, as well as whether the patient's condition warrants admission as an inpatient, it is unfair that the hospital is penalized if that procedure happens to be on the inpatient list.

CMS should also consider policy changes that would allow hospitals to change to the appropriate inpatient or outpatient status after patient discharge but before the patient or payor is billed. CMS' requirements should focus on ensuring that the beneficiary receives appropriate, quality care and the hospital bills correctly for the care given instead of relying on antiquated rules put in place when the inpatient prospective payment system was introduced and there was fear that some hospitals may try to game IPPS by making admissions outpatient and billing under what was, at that time, still a cost-based payment methodology. A change in this area would be applauded by the hospital industry and help smaller facilities to better focus limited utilization review resources on the quality of care instead of spending an inordinate amount of time chasing physicians different wording on a piece of paper before the patient is discharged.

Multiple Diagnostic Imaging Procedures

Under the proposed rule, hospitals will experience a decrease in payments for some diagnostic procedures that are performed in the same session with the patient. Current payment structure was initially established based on the cost of these procedures. Therefore, in order to still pay hospitals for their cost, this change must be budget neutral within the Radiology area. It is also essential that similar payment systems be adopted concurrently for free-standing radiology providers so as to avoid creating further inequities.

Interrupted Procedure Payment Policies

The resources and staff time involved in a failed or interrupted procedure equal or exceed that of a successfully completed procedure, we oppose the planned payment reduction to 50% of the APC amount.

OPPS 2006 Comments

September 16, 2005

Page 4 of 4

Jewish Hospital Healthcare Services, Inc., appreciates the opportunity to submit these comments. If you have any questions, please feel free to contact me.

Sincerely,

A handwritten signature in black ink, appearing to read "D. Gregory Dorris". The signature is fluid and cursive, with the first name "D." being prominent.

D. Gregory Dorris
Vice President of Finance/Revenue Cycle
Jewish Hospital Healthcare Services, Inc.

CC: Mark B. Carter, Senior Vice President and Chief Financial Officer

Submitter : Brian Abraham
Organization : MedImmune
Category : Drug Industry

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-1501-P-505-Attach-1.PDF



September 16, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, Maryland 21244-8016

Dear Dr. McClellan:

MedImmune is pleased to have the opportunity to comment on the proposed rule (CMS-1501-P) for the Medicare 2006 Hospital Outpatient Prospective Payment System (HOPPS). MedImmune is a fully integrated biotechnology company that manufactures and markets drugs administered in the hospital outpatient department (HOPD) to Medicare beneficiaries. Specifically, hospitals provide our drugs Ethyol[®] (amifostine) as part of anti-cancer therapies, FluMist[®], the only live, attenuated influenza vaccine (intranasal administration), and CytoGam[®] (cytomegalovirus intravenous immunoglobulin, human) for transplant patients.

We appreciate all of the effort CMS has made to ensure that Medicare patients access the treatments they need, regardless of the setting of care. This proposed rule is the latest example of returning independent medical decision making to the health care team, rather than forcing physicians and other health care providers to navigate through artificial barriers imposed by a complex system. We are especially pleased with the reimbursement rate proposed for Part B drugs administered in the HOPD.

As the manufacturer of FluMist, we have some concerns which we addressed to the Medicare Payment Advisory Commission (MedPAC) during its August 17 meeting; subsequently, MedPAC has made recommendations we endorse and will reiterate in our comments.

Non Pass-Throughs

MedImmune supports CMS's proposal to continue the packaging thresholds for non pass-through drugs and biologicals at the 2005 level of \$50 or higher to be separately payable. In addition, we are particularly appreciative that CMS again has stated that 5HT₃ anti-emetic products will be exempt from the packaging threshold. CMS is correct in its statement that "side effects are often debilitating" for patients undergoing chemotherapy and other treatments for cancer, including radiation therapy.¹ The more access that Medicare patients have to these prophylactic therapies, the more likely the patients will

¹ 70 Fed. Reg. 42723.

be able to complete their primary treatments, and live healthier lives with fewer complications.

When determining average acquisition cost as mandated by the Medicare Modernization Act², we also commend CMS for measuring cost data as a true average, or mean, rather than the median of reported costs, as was done in previous HOPPS rules. We agree with CMS that it is prudent not to use the Government Accountability Office (GAO) data nor hospital-reported costs to determine average acquisition cost because of timing and accuracy issues.³ We agree with CMS that reimbursing hospitals for drugs using the same system as for physicians is fair and justified. This ASP+6% system also will help ensure that Medicare beneficiaries access the therapies they need in the most appropriate setting. Our only concern is that if there is a product where there happens to be a significant negative margin between hospitals' costs and the reimbursement rate at ASP+6%, that CMS does not have an alternative payment method in place. In these cases, we urge CMS to implement an upward equitable adjustment by invoking Section 1833(t)(2)(E) of the Act.

With respect to pharmacy handling costs, we are encouraged by CMS's proposal to add two percent to each drug payment.⁴ However, during this first year of providing payments for pharmacy handling, there may still exist inequities for the handling of certain drugs. Even if a drug has a relatively low cost, it may require specialized handling, as the codes you propose seem to demonstrate. Therefore, the two percent may not be adequate to pay the hospital fully for handling the drug. We agree with the MedPAC recommendation that CMS reexamine the amount of the handling fees, and delay implementing the codes for pharmacy handling.⁵ We also agree that CMS should recalculate the handling fees by soliciting additional input from stakeholders in the hospital community, especially hospital-based cancer centers, where pharmacy handling is integral to their operations.

Vaccines

Historically, under HCPPS, CMS has paid for injectable influenza vaccines on a reasonable cost basis, reflecting some of the unique attributes of these products, and has paid separately for the related administration service. In the proposed rule, CMS assigns a status indicator for all influenza vaccines that specifies that these vaccines are to be paid on a reasonable cost basis, except for FluMist, the live, attenuated influenza vaccine administered intranasally. There is no plausible basis for treating FluMist differently, as the same reasons compelling CMS to pay for influenza vaccines on a reasonable cost basis in the outpatient setting also apply to FluMist. Therefore, we request that CMS pay for FluMist (CPT code 90660) on a reasonable cost basis, and assign the Status Indicator "L" to this code. This request is consistent with MedPAC's recommendation.⁶

² Social Security Act, § 1833(t)(14)(A)(iii).

³ 70 Fed. Reg. 42726-7.

⁴ 70 Fed. Reg. 42730.

⁵ Panel's Recommendations, posted at <http://www.cms.hhs.gov/faca/apc/panel-recommendations.pdf>

⁶ Ibid.

Under the proposed rule, the payment rate for administering FluMist would be \$5.00 (CPT codes 90473 and 90474), compared to the proposed rate of \$23.36 for administering other influenza vaccines. Hospitals utilize similar resources when administering all types of influenza vaccines – injected or intranasal – and thus these administration services should be assigned to the same APC. In light of recent experiences with shortages of flu vaccines, it is critical that Medicare reimbursement for the vaccine and the related administration service ensure that there are no impediments to access to the nasal mist influenza vaccine. Any such impediments could jeopardize the ability of beneficiaries, and especially those that they come in contact with, to be protected against the influenza virus. Therefore, we request that CMS assign the intranasal administration of influenza vaccine to HCPCS code G0008, which is assigned to APC 0350, in order for all influenza vaccine administrations to be treated equitably. This request also is consistent with the MedPAC recommendation.⁷

Conclusion

Once again, MedImmune appreciates the opportunity to provide these comments on the HOPPS proposed rule for 2006. We hope that CMS will make the adjustments we have commented on, and would be delighted to provide further input and offer our expertise, particularly pertaining to vaccines. Please contact Brian Abraham, Associate Director for Reimbursement, at abrahamb@medimmune.com or (301) 398-4626 with any questions you have about these comments or other matters regarding Medicare programs.

Sincerely yours,

/s/

Caroline York
Vice President
Reimbursement and Government Affairs

⁷ Ibid.

Submitter : Masahide Tanigaki
Organization : Hitachi
Category : Private Industry

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

8/23/05 Hitachi Letter to Hon. Mark B. McClellan, M.D.; re Proton Beam Therapy Payment Classification

CMS-1501-P-506-Attach-1.PDF

HITACHI

Inspire the Next

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August 23, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW, Room 314 G
Washington, DC 20201

Re: Proton Beam Therapy Payment Classification

Dear Dr. McClellan:

As you are aware, proton therapy is one of the most promising technologies for cancer treatment. Currently, over 46,000 cancer patients have been treated with protons in many institutions around the world, including three institutions currently providing proton beam therapy in the United States. Positive clinical results from these facilities have stimulated worldwide interest in the clinical applications of proton therapy. Hitachi America, Ltd. is one of the few leading global companies that supply proton beam equipment, and our parent company, Hitachi, Ltd., continues to be one of the leading manufacturers, developers and implementers of new technology in this area. Consequently, we have been contacted by numerous institutions, which are interested in adding proton therapy to their arsenal of weapons in the fight against cancer, and we also are in the process of working with M.D. Anderson in bringing to life the 4th proton therapy cancer treatment center in the United States.

Proton beam therapy is in an early stage of clinical adoption. The required equipment is significantly more expensive to purchase and maintain than standard radiation treatment equipment. A typical proton beam therapy center requires between \$70-\$125 million and more than three years to develop. As a result, the number of sites establishing proton beam therapy centers has not kept pace with the clinical demand for the service. For those sites establishing centers, cost continues to be a major concern, which underscores the importance of maintaining adequate Medicare payment for the technology. It is critical that CMS OPPS continues to work with the providers of proton therapy to understand and analyze the data for classification and payment, as was clearly seen by the CY 2006 proposed rule, to ensure the economic viability of both existing facilities and those in various stages of construction and development.


We strongly support the classification and payment rates for simple, intermediate and complex proton therapies as proposed in the CMS CY 2006 OPPS rule. We urge CMS to make the proposed rule its final rule for CY 2006.

This will ensure that the Nation's premier cancer treatment centers have the ability to provide cancer patients with this successful therapy.

We believe that proton therapy is responsible for improving health outcomes, quality of life and our standard for cancer treatment. Appropriate payment rates for proton beam therapy will help to ensure this leading-edge cancer therapy is available to those who need it.

Thank you for your prompt attention to this critical issue.

Sincerely,



Masahide Tanigaki
Executive Vice President and General Manager
Hitachi America Ltd.

Submitter : Mr. Shabir Somani

Date: 09/16/2005

Organization : UW Medicine

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam,

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 mandated that MedPAC report on whether the Secretary should adjust payments in the outpatient prospective payment system (PPS) for pharmacy and nuclear medicine handling costs. This question was posed in large part since Medicare begins paying for certain drugs, biologicals and radiopharmaceuticals based on acquisition costs in 2006. Historically, payment rates for these were higher, including resources for covering handling costs.

Subsequently, a June 2005 report was generated by MedPAC concluding that handling costs are significant and warrant adjustment. As per MedPAC's recommendations, the Secretary should "instruct hospitals to submit charges" for a defined set of handling fee APCs and base payment rates on those submitted charges. MedPAC's report indicated that handling costs make up "26 percent to 28 percent of pharmacy departments' direct costs."

Instead of accepting MedPAC's analysis, CMS proposes to pay only an additional 2 percent of the ASP scaled for budget neutrality to cover the handling costs of these drugs.

I believe this reimbursement formula does not adequately cover drug, biological and radiopharmaceutical handling costs which include the following:

- Storage
- Preparation
- Transport
- Disposal

Additionally, key management and oversight functions of pharmacy and nuclear medicine programs include record keeping, human resource management, compliance, safety, and quality assurance among others.

Ultimately, inadequate reimbursement to hospital outpatient departments will negatively impact the quality, safety and level of their services. As a viable alternative, I support the proposal being made by the Association of Community Cancer Centers (ACCC) that CMS consider an allowance of 8% to cover pharmacy handling and overhead expenses for all drugs reimbursed under the hospital OPPS, in addition to ASP + 6% to cover the drug acquisition cost.

Thank you for the opportunity to express my concerns on this vital issue and I look forward to a meaningful adjustment in the upcoming final rule.

Sincerely,

Shabir

Shabir M. Somani somani@u.washington.edu
Director and Associate Professor UWMC: (206) 598-6060
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University of Washington Academic Medical Center FAX: (206) 598-6075

This message, and any attachments to it, is protected by quality assurance/peer review and/or work product confidentiality. It is intended only for a specific recipient or recipients. If you have received this message in error, please notify the sender immediately.

Submitter : Dr. Fremont Wirth
Organization : American Association of Neurological Surgeons
Category : Health Care Professional or Association

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

Sec Attachment

CMS-1501-P-508-Attach-1.PDF

AMERICAN ASSOCIATION OF
NEUROLOGICAL SURGEONS

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President
FREMONT P. WIRTH, MD
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American
Association of
Neurological
Surgeons

CONGRESS OF
NEUROLOGICAL SURGEONS

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President
NELSON M. OYESIKU MD, PHD
Emory University
Atlanta, Georgia

September 16, 2005

Mark B. McClellan, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

**RE: Medicare Program; Proposed Changes to the Hospital Outpatient
Prospective Payment System and Calendar Year 2006 Payment Rates;
CMS-1501-P**

Dear Dr. McClellan:

The American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), organized neurosurgery in the United States, appreciate the opportunity to comment on the above referenced proposed rule published in the *Federal Register* on July 25, 2005.

Stereotactic Radiosurgery Proposals

We would like to comment on the three proposals made by CMS in the discussion of Stereotactic Radiosurgery (SRS) on pages 42708 and 42709 of the July 25, 2005 *Federal Register*. Before we address the specific issues raised by CMS in the proposed rule, we would once again like to provide you with some additional background and information about stereotactic radiosurgery.

I. Background

Stereotactic radiosurgery was conceived by the Swedish Neurosurgeon Lars Leksell in 1951 as stereotactic delivery of high dose ionizing radiation to non-invasively extirpate lesions deep within the brain. The first commercially available radiosurgical device was designed in 1967 and radiosurgery was brought to the U.S. in the mid 1980s. Since 1951, neurosurgeons have played an integral role in the development of this technology. The neurosurgeon's role has been not only to decide on the appropriateness of radiosurgery vs. conventional open surgery, but to perform many of the most critically important aspects of the procedure included within the description of 61793. Thus, the neurosurgeon is responsible for secure and appropriate placement of the frame; determination of the images

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to acquire; checking the quality of these images; fusing of various imaging modalities (i.e. MRI, CT, angiogram--when appropriate); frame removal and wound management--which may require sutures; and immediate post-operative care. Radiosurgery isodose planning is performed as a collaborative effort, combining the neurosurgeon's expertise in surgical neuroanatomy and physiology, with the expertise in dose selection and radiation safety possessed by the radiation oncologist and radiation physicist.

Stereotactic Radiosurgery Requires a Multidisciplinary Team Led by Neurosurgeons.

Although SRS is a procedure that requires the involvement of a neurosurgeon, radiation oncologist and medical physicist, it is a surgical procedure that should be overseen and managed by a neurological surgeon. Neurosurgeons undergo post-graduate education in neuro-anatomy, neuro-physiology, neuro-pharmacology, neuro-radiology, neuro-pathology, clinical neurology, and clinical neurosurgery during 6-7 years of residency training focused entirely on the brain and spine. This training includes multiple cadaveric brain dissections; hours of perfecting three-dimensional operative neuro-anatomy both in the lab and in the operating room; separate 3-6 month rotations with board-certified sub-specialists in neuro-radiology, neuro-pathology, and neurology; as well as clinical rotations in operative neurosurgery and stereotactic radiosurgery. Residents must demonstrate mastery of this knowledge in written and oral exams to complete their residency and achieve board certification.

In contrast, radiation oncologists have a four year residency to learn about all the cancer throughout the body, with little or no time devoted to formal review of neuroanatomy or neurophysiology. While some may have exposure to stereotactic radiosurgery as part of their training, they may not necessarily undergo training in any of these subspecialty areas, nor is such training required for completion of residency training or board certification. Primary brain tumors comprise less than 2% all cancers, and brain metastasis occur in less than 10% of all cancer patients, less than half of which are currently candidates for radiosurgery. Thus, the lack of neuroscience expertise within the field of radiation oncology is neither surprising nor inappropriate. However, most radiation oncologists are not trained to be primarily responsible for the radiosurgical treatment of neoplastic lesions of the brain and spine without the supervision of a neurosurgeon. Moreover, it is unlikely that most radiation oncologists receive any training whatsoever for the treatment of *functional* neurologic disorders (i.e. facial pain, movement disorders, depression etc...) and vascular malformations, which are increasingly being treated with stereotactic radiosurgery. Thus, the use of high dose ionizing radiation for lesions of the brain or spine without neurosurgical involvement is not in the public's best interest.

Stereotactic Radiosurgery is Not New Technology. Stereotactic radiosurgery is not new technology. The codes should therefore be consistent with those for established neurosurgical procedures, as neurosurgeons developed this treatment modality and have established its efficacy over more than two decades. The most appropriate placement for this procedure is in a surgical APC.

Radiosurgery Coding and Payment Difficulties. CMS has made several coding changes over the last few years regarding stereotactic radiosurgery. In 2002, CMS created two new HCPCS codes, G0242 and G0243, to replace the single HCPCS code G0173. The G0173 code was used as a single code for the facility payment associated with CPT code 61793 for outpatient stereotactic radiosurgery. However, the code 61793 is still used for facility coding

for inpatient radiosurgical procedures for both cobalt⁶⁰ and linear accelerator based treatments by all insurers other than Medicare.

The use of separate codes for planning and treatment for a single stage surgical procedure is unnecessary, inappropriate and confusing, and has had significant and unforeseen consequences for both hospitals and physicians. From a practical standpoint, changes in SRS coding in recent years have created unnecessary work for clerical and administrative personnel and caused problems for hospitals and insurance companies. Having one code to describe all modalities of SRS would be much simpler and more accurate and would eliminate the difficulty that some facilities have in obtaining reimbursement for these procedures. We therefore have repeatedly urged CMS to eliminate the G-codes and return to using CPT code 61793 to describe the outpatient facility payments for SRS.

II. Comments on the Current Proposed Rule

We will now address the specific proposals related to SRS contained in the proposed rule.

- a. CMS proposes to make no changes to the APC placement of SRS treatment delivery codes: HCPCS codes G0173 *Linear Accelerator Stereotactic Radiosurgery*, G0243 *Multisource Proton Stereotactic Treatment*, G0251 *Linear Accelerator Based Stereotactic Radiosurgery*, G0339 *Robotic Linear Radiosurgery*, and G0340 *Robotic Linier Radiosurgery Factions 2-5*. CMS has stated that it proposes to keep these procedures in new technology APCs rather than moving these codes to clinical APCs.

The AANS and CNS do not support this proposal and contend that these procedures are not new technology and should therefore be moved to the appropriate surgical APCs.

- b. CMS is proposing to discontinue use of HCPCS codes G0242 *Cobalt⁶⁰ Based Stereotactic Radiosurgery Planning* and G338 *Cobalt⁶⁰ Based Stereotactic Radiosurgery* delivery and instead instruct hospitals to bill charges for SRS planning using the CPT codes that most accurately reflect the services provided.

The AANS and CNS agree that CPT codes are more appropriate than G codes for reporting charges for these procedures and that for SRS, planning and delivery are always linked. One is not done without the other. The most appropriate code for reporting services connected with SRS is CPT code 61793.

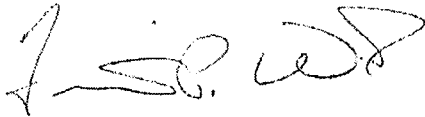
- c. Finally, CMS has asked for comments on the "clinical, administrative, or other concerns that could arise if CMS were to bundle cobalt⁶⁰ based SRS planning services, currently reported using HCPCS code G0242 and proposed by Calendar Year 2006 to be billed using the appropriate CPT codes for planning services, into the cobalt⁶⁰ based SRS treatment services, currently reported under the OPPS using HCPCS code G0243. Under such a scenario, the SRS treatment service described by HCPCS code G0243 would be placed in a higher paying New Technology APC to reflect payment for the costs of the SRS planning and delivery as an integrated service. Hospitals would be prohibited from billing other radiation planning services along with the cobalt⁶⁰ based SRS treatment delivery code. In contrast to cobalt⁶⁰ based SRS coding, we would not consider bundling the planning for linear accelerator-based SRS with the treatment

delivery services, given the various timeframes for planning that may occur with linear accelerator-based SRS."

The AANS and CNS support placing SRS in a higher paying surgical APC. In addition, we are concerned about separate policies for cobalt⁶⁰, linear accelerator, and other modalities. All modes of SRS should be treated the same and we therefore oppose your proposal to implement different policies for cobalt⁶⁰ and linear accelerator-based SRS. Again, we reiterate our suggestion that CMS return to using 61793 to describe all modes of SRS. This was the policy until several years ago, and it would simplify matters greatly.

Again, thank you for the opportunity to comment. We acknowledge the hard work and dedication of the men and women at CMS who strive to produce clear and understandable explanations for regulations that are inherently complex and detailed. Please let us know if you need additional information on this issue. We believe that it is essential that CMS seek the input from the neurosurgical community on all matters and policy decisions related to SRS and we are therefore happy to assist you however we can.

Sincerely,



Fremont P. Wirth, MD, President
American Association of Neurological Surgeons



Nelson M. Oyesiku, MD, President
Congress of Neurological Surgeons

Staff Contact:

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Submitter : Ajit Singh, Ph.D.

Date: 09/16/2005

Organization : SIEMENS

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

Siemens Letter to Hon. Mark B. McClellan, M.D., Ph.D.; re Proton Beam Therapy Payment Classification

CMS-1501-P-509-Attach-1.PDF



The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 314 G
Washington, DC 20201

Re: Proton Beam Therapy Payment Classification

Dear Dr. McClellan:

Siemens Medical Solutions strongly support the classification and payment rates for simple, intermediate and complex proton therapies as proposed in the CMS CY 2006 OPPS rule. We urge CMS to make the proposed rule its final rule for CY 2006. In the Proposed Calendar Year (CY) 2006 Rule: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY'06 Payment Rates (CMS-1501-P), CMS proposed rule we note the following as it relates to proton therapy:

1. The proposed rule maintains separate classifications for simple, intermediate and complex proton therapies (CPT-4 codes 77520, 77522, 77523 and 77525, respectively).
2. CMS also proposes to move intermediate and complex proton therapies (CPT 77523 and 77525) from a New Technology APC (1511) into a clinical APC (0667).
3. Payment rates are proposed to be \$764.74 under APC 0664 for simple proton therapies (77520 and 77522) and \$914.92 under APC 0667 for intermediate and complex therapies (77523 and 77525).

Maintaining separate APC rates for proton therapies of varied complexity is necessary to differentiate between resource demands of different treatment levels.

The proposed rates more accurately reflect the significant capital demands associated with developing and high operating costs of running a proton therapy center.

Also, it should be noted that this technology is in the early stages of diffusion and as such the number of claims data should be monitored carefully, as it is expected to be modest for the next 2-3 years, with an outlook to supporting patient access to proton beam therapy.

We strongly support the classification and payment rates for simple, intermediate and complex proton therapies as proposed in the CMS CY 2006 OPPS rule. We urge CMS to make the proposed rule its final rule for CY 2006.

This will ensure that the Nation's premier cancer treatment centers have the ability to provide cancer patients with this successful treatment.

Currently, over 46,000 cancer patients have been treated with protons in many institutions around the world, including three institutions currently providing proton beam therapy in the United States. Positive clinical results from these facilities have stimulated worldwide interest in the clinical applications of proton therapy and consequently numerous facilities are in the planning or construction phases

Proton beam therapy is in an early stage of clinical adoption. The required equipment is significantly

Siemens Medical Solutions USA, Inc.

Oncology Care Systems Group 4040 Nelson Avenue
Concord, CA 94520

Tel: +1 (925) 246-8200
Fax: +1 (925) 246-8284



more expensive to purchase and maintain than standard radiation treatment equipment. A typical proton beam therapy center requires between \$70-\$125 million and more than three years to develop. As a result, the number of sites establishing proton beam therapy centers has not kept pace with the clinical demand for the service. For those sites establishing centers, cost continues to be a major concern, which underscores the importance of maintaining adequate Medicare payment for the technology. It is critical that CMS OPPS continues to work with the providers of proton therapy to understand and analyze the data for classification and payment, as was clearly seen by the CY 2006 proposed rule, to ensure the economic viability of both existing facilities and those in various stages of construction and development.

Proton therapy is responsible for improving health outcomes, quality of life and our standard for cancer treatment. Appropriate payment rates for proton beam therapy will ensure this leading-edge cancer therapy is available to those we serve.

Thank you for your prompt attention to this critical issue.

Sincerely,

A handwritten signature in black ink that reads "Ajit Singh". The signature is fluid and cursive, with the first and last names clearly distinguishable.

Ajit Singh Ph.D.
President, Siemens Oncology Care Systems
Siemens Medical Solutions

Siemens Medical Solutions USA, Inc.

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CMS-1501-P-510

Submitter : Marcel R. Marc

Date: 09/16/2005

Organization : Varian

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

8/11/05 Varian Letter to Hon. Mark B. McClellan, M.D., Ph.D.; re Proton Beam Therapy Payment Classification

CMS-1501-P-510-Attach-1.PDF

VARIAN

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www.varian.com

August 11, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 314 G
Washington, DC 20201

Re: Proton Beam Therapy Payment Classification

Dear Dr. McClellan:

In the Proposed Calendar Year (CY) 2006 Rule: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY'06 Payment Rates (CMS-1501-P), CMS proposed rule we note the following as it relates to proton therapy:

1. The proposed rule maintains separate classifications for simple, intermediate and complex proton therapies (CPT-4 codes 77520, 77522, 77523 and 77525, respectively).
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The proposed rates more accurately reflect the significant capital demands associated with developing and high operating costs of running a proton therapy center.

Also, it should be noted that this technology is in the early stages of diffusion and as such the number of claims data should be monitored carefully, as it is expected to be modest for the next 2-3 years, with an outlook to supporting patient access to proton beam therapy.

We strongly support the classification and payment rates for simple, intermediate and complex proton therapies as proposed in the CMS CY 2006 OPPS rule. We urge CMS to make the proposed rule its final rule for CY 2006.

This will ensure that the Nation's premier cancer treatment centers have the ability to provide cancer patients with this successful treatment.

Currently, over 46,000 cancer patients have been treated with protons in many institutions around the world, including three institutions currently providing proton beam therapy in the United States. Positive clinical results from these facilities have stimulated worldwide interest in the clinical applications of proton therapy and consequently numerous facilities are in the planning or construction phases

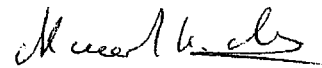
Proton beam therapy is in an early stage of clinical adoption. The required equipment is significantly more expensive to purchase and maintain than standard radiation treatment equipment. A typical proton beam therapy center requires between \$70-\$125 million and more than three years to develop. As a result, the number of sites establishing proton beam therapy centers has not kept pace with the clinical demand for the service. For those sites establishing centers, cost continues to be a major concern, which underscores the importance of maintaining

adequate Medicare payment for the technology. It is critical that CMS HOPPS continues to work with the providers of proton therapy to understand and analyze the data for classification and payment, as was clearly seen by the CY 2006 proposed rule, to ensure the economic viability of both existing facilities and those in various stages of construction and development.

Proton therapy is responsible for improving health outcomes, quality of life and our standard for cancer treatment. Appropriate payment rates for proton beam therapy will ensure this leading-edge cancer therapy is available to those we serve.

Thank you for your prompt attention to this critical issue.

Sincerely,

A handwritten signature in dark ink, appearing to read "Marcel R. Marc", with a horizontal line drawn underneath the name.

Marcel R. Marc

Submitter : Dr. Robert Hawes
Organization : American Society for Gastrointestinal Endoscopy
Category : Health Care Professional or Association

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-511-Attach-1.DOC



September 15, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates

Dear Doctor McClellan:

The American Gastroenterological Association (AGA) is the nation's oldest not-for-profit medical specialty society, and the largest society of gastroenterologists, representing more than 14,000 physicians and scientists who are involved in research, clinical practice, and education on disorders of the digestive system. The American Society for Gastrointestinal Endoscopy (ASGE) represents more than 8,000 physicians who specialize in the use of endoscopy to diagnose and treat gastrointestinal diseases and conditions.

The AGA and ASGE welcome the opportunity to comment on the proposed changes to the hospital outpatient prospective payment system for 2006.

Pass-Through Device Categories

We are pleased that CMS has addressed its policy of whether devices inserted through natural orifices should be eligible to qualify for "pass-through" payment under the hospital outpatient prospective payment system. CMS is to be commended for recognizing that a traditional definition of surgical incision limits access to innovative, less invasive technologies that can be inserted through an orifice. These technologies offer benefits for Medicare beneficiaries and avoidance of more invasive, costly surgery.

By way of implementation, CMS proposes to modify the current interpretation of regulation §419.66(b)(3) to consider devices pass-through eligible if inserted or implanted through a natural

or surgically-created orifice within the scope of surgically implanted devices, as well as those that are inserted or implanted through a surgically created incision. While this interpretation resolves the need to establish the existence of a traditional surgical incision to insert/implant a device through an orifice, we suggest that regulatory language be modified to institutionalize this change.

Recommendation:

We request consideration by CMS to change the regulation to read:

§419.66 (b)(3) The device is an integral and subordinate part of the service furnished, is used for one patient only, comes in contact with human tissue, and is implanted or inserted, through a natural or surgically created orifice or through a surgically created incision, whether or not the device remains with the patient when the patient is released from the hospital.

Device-Dependent APCs

We are concerned about the proposed reduction in APC 0384, GI stenting procedures, of 14.5% for 2006. This would also represent a cumulative reduction of 16.5% since CY 2004. The payment rate for this APC is clearly inadequate to cover the cost of the stents and the hospital's associated labor and overhead for these procedures.

As indicated by a number of presenters at the August APC Advisory Panel meeting, CMS is currently setting payment rates using claims where C codes were not reported. For device dependent APCs, there are substantial inconsistencies on the part of hospitals in the billing for the C code for the device and for the related procedure code. It is for this reason that CMS has mandated for 2005 billings that hospitals are required to report the C code for device dependent APCs along with the charge for the procedure. However, the 2005 claims data is not available for use in determining the 2006 HOPPS rates. For 2006, CMS is using data for 2004 claims when the billing of the C code was optional. An analysis of the data for claims assigned to APC 0384 indicates that the median costs of claims with C codes reported are substantially higher than the median cost for claims with the procedure code and a C code if one was reported.

CMS has decided to use all claims for gastrointestinal stent procedures that would otherwise meet its single claim standard regardless of whether a C code was reported. The reason for this decision was CMS' concern that for many device dependent APCs, using only claims for which a C code was reported might result in small number of claims used to calculate payment and/or the belief that these claims might not be representative of hospital costs. While this may or may not be true for other device dependent APCs, it is our judgment that this rationale does not apply to the Gastrointestinal stent procedures. First, there would be an adequate number of these claims to reliably determine median costs for this APC. Second, we think the resultant median costs would be a much more accurate representation of actual costs of providing the stent procedures which involve disposable devices that can cost up to \$1,900.

At the August APC Advisory Committee meeting, Boston Scientific, one of the major manufacturers of stents, presented this issue. The Committee recommended to CMS that it use only claims which included a C code in the calculation of median costs of APC 0384. We agree with this recommendation and urge that CMS adopt this change for the final rule.

However, a second recommendation of the APC Advisory Committee relating to this APC was for CMS to split the GI stent APC into two groupings: ERCP with stent placement and all other stent codes. The rationale for this recommendation apparently flows from the erroneous belief that the ERCP stent placement codes require substantially less time to perform because of the use of fluoroscopy. We disagree with the recommendation and urge that CMS leave APC 0384 intact for 2006. With regards to the distinction between ERCP and other stent placement procedures, we would note that procedures involving stenting of the gastrointestinal lumen require deployment of stents across a stenotic region. This is true for both stent placement in the biliary tree (ERCP) and stent placement elsewhere in the gastrointestinal tract. The area of stenosis is most typically caused by an end stage malignancy and frequently these patients have very limited treatment options. Irrespective of the location to be stented, similar techniques are employed to accomplish the procedure. Specifically, the narrowed region is approached endoscopically. Under continuous fluoroscopy monitoring contrast is injected to define the stenosis, a guidewire is placed across the region of narrowing under fluoroscopic visualization, a stent is placed across the narrowing, and then the stent is deployed. For all stenting procedures, fluoroscopy is an integral component of the service in that the physician cannot visualize the distal stent due to tumor stenosis (or position within the bile duct). Radiological monitoring is needed to insure that the ultimate position of the stent satisfactorily extends across the entire luminal stenosis.

For both biliary and non biliary stent placement, radioopaque contrast is injected across the luminal narrowing to verify the extent of narrowing and to assess for any fistulas. In most settings, this injection of contrast is performed with an ERCP type cannula, whether the tumor is within the esophagus, colon, bile duct or elsewhere. Similarly, the guidewires employed in stent placement are the same as those used for ERCP. Thus, stent placement in the biliary tree and elsewhere in the gastrointestinal tract requires similar equipment, supplies, techniques and fluoroscopic assistance. Therefore, we respectfully disagree with the Advisory Committee regarding their comments about the duration of these procedures. The selection bias inherent in this service affords a patient population enriched with elderly, cachexic and debilitated individuals who stand to gain some benefit when non surgical palliation of their malignant gastrointestinal obstruction occurs. Rather, we suggest that physician and fluoroscopy time for performance of stent placement is determined more by nuances arising from gaining access across the tumor, sedating the patient and fluoroscopic monitoring, rather than the inherent location of the malignancy.

Recommendation:

We encourage CMS to recompute the median cost of APC 0384 using claims with appropriately reported C codes as recommended by the APC Advisory Panel. As an alternative, we urge CMS to freeze payments rates for APC 0384 and other device-dependent APCs for 2006. This would only need to be a one-year temporary measure since rates set for 2007 will use 2005 claims where there is mandatory billing of C codes.

We also urge CMS not to adopt the recommendation of the APC Advisory Committee to split the GI stent APC into two groupings: ERCP with stent placement, and all other stent codes. We believe CMS will have much more accurate data on the costs of device dependent APCs in 2006 when use of C codes will be mandatory in the claims data used to construct the APC rates. It

would be preferable not to modify the APC assignment of the stent codes at this time until better data is available before considering any APC reassignment of these codes.

Addendum B - CPT Code 91035

In the 2006 proposed rule that was published in the July 25, 2005 *Federal Register*, CMS proposed to move CPT 91035 (Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation) from APC 1506 to APC 0361, *Level II Alimentary Tests*. We were concerned about the lack of clinical coherence with movement of this procedure to APC 0361 which would have resulted in a 52% payment decrease. We appreciate the agency's prompt and appropriate response for recognizing that the proposed APC change was an error; as per the August 26 *Federal Register* correction notice, CPT 91035 is proposed to remain in APC 1506 for 2006.

Recommendation:

We support retaining this CPT code 91035 in APC 1506 until better data is available before considering any APC reassignment of this procedure.

Interrupted Procedures

We wish to comment on the application of the proposed 50 percent reduction in payment for procedures reported with a 52 modifier. Our concern relates to the capsule endoscopy of the esophagus (PillCam ESO). We agree there is reduction in the professional component associated with this procedure if the ileum is not visualized. However, we disagree that there is absolutely no reduction in the resources incurred for the technical component or facility costs whether or not the ileum is visualized, and recommend that the proposed payment reduction not be applied on this procedure.

The manufacturer of this technology had requested a new technology APC for this procedure. Their application was denied on the grounds that the procedure could be adequately described by an existing code, namely, CPT Code 91110 with a 52 modifier. We would note that Code 91110 is defined as follows:

Gastrointestinal tract imaging, intraluminal (e.g. capsule endoscopy), esophagus through ileum, with physician interpretation and report.

(Append modifier 52 if the ileum is not visualized).

The rationale for the proposed 50 percent reduction in payment for procedures reported with a 52 modifier is based on the assumption that the resource costs are substantially diminished. This may well be true for a discontinued radiological service which seems to be the main focus of the proposal. However, we do not think the reduction in payment for a capsule endoscopy of the esophagus is appropriate or consistent with the HOPPS objective to pay appropriately based on the resources required to produce a service.

Certainly, it is consistent with the definition of code 91110 that there is a reduction in the professional component associated with the interpretation of the images when the gastrointestinal tract from the esophagus through the ileum is not completely visualized. This is because the physician has fewer images to interpret to obtain a diagnosis in those instances when only the esophagus is visualized. However, there is no comparable reduction in the resources required for the technical component or the facility costs covered by the APC rate for Code 91110 whether or

not the ileum is visualized. This is because the staff, equipment, overhead and, most importantly, supply costs associated with the disposable capsule camera, are identical for all capsule endoscopy procedures, whether only the esophagus or the upper gastrointestinal and small intestinal tract is visualized. As the costs for the technical component costs are essentially identical, this does not represent a "reduced service" from the standpoint of hospital resource costs.

Obviously the proposal to provide for a 50 percent reduction in payment for services for which a 52 modifier is appended is considerably broader than the capsule endoscopy procedure.


Recommendation:

If CMS, however, decides to proceed with this proposed policy in the final rule for radiobiology and other services not involving anesthesia, we strongly urge CMS not to apply this reduction to capsule endoscopy of the esophagus. This could be accomplished by a variety of actions including the following:

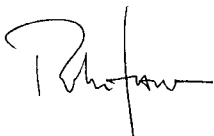
- Exempt hospitals from being required to report Code 91110 without a 52 modifier for capsule endoscopy of the esophagus or in other instances when the ileum is not visualized.
- If the decision is to require the use of the 52 modifier, establish an administrative exception so that intermediaries would not reduce payment under HOPPS in any situation where Code 91110-52 is reported. A reduction in payment would of course still be applicable for the professional component.
- Establish a temporary code to be used by hospitals to report the technical component of the capsule endoscopy of the esophagus procedure. The payment should be equal to the APC rate for Code 91110.

Thank you for consideration of our comments on the 2006 hospital outpatient prospective payment proposed rule. If we may provide any additional information on our comments, please contact Anne Marie Bicha, AGA Director of Regulatory Affairs at 301-654-2055, ext. 664 or abicha@gastro.org or Bernard Patashnik, ASGE, at 202-833-0007 or bpatashnik@aol.com.

Sincerely,



David A. Peura, MD
AGA President



Robert Hawes, MD
ASGE President

Submitter : Dave Van Gorp
Organization : Medtec
Category : Private Industry

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

8/7/05 Medtec Letter to Hon. Mark B. McClellan, M.D., Ph.D.; re Proton Beam Therapy Payment Classification

CMS-1501-P-512-Attach-1.PDF



The Science of Life for the Art of Living™

August 7, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 314 G
Washington, DC 20201

Re: Proton Beam Therapy Payment Classification

Dear Dr. McClellan:

In the Proposed Calendar Year (CY) 2006 Rule: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY'06 Payment Rates (CMS-1501-P), CMS proposed rule we note the following as it relates to proton therapy:

1. The proposed rule maintains separate classifications for simple, intermediate and complex proton therapies (CPT-4 codes 77520, 77522, 77523 and 77525, respectively)
2. CMS also proposes to move intermediate and complex proton therapies (CPT 77523 and 77525) from a New Technology APC (1511) into a clinical APC (0667).
3. Payment rates are proposed to be \$764.74 under APC 0664 for simple proton therapies (77520 and 77522) and \$914.92 under APC 0667 for intermediate and complex therapies (77523 and 77525)

Maintaining separate APC rates for proton therapies of varied complexity is necessary to differentiate between resource demands of different treatment levels.

The proposed rates more accurately reflect the significant capital demands associated with developing and high operating costs of running a proton therapy center.

Also, it should be noted that this technology is in the early stages of diffusion and as such the number of claims data should be monitored carefully, as it is expected to be modest for the next 2-3 years, with an outlook to supporting patient access to proton beam therapy.

We strongly support the classification and payment rates for simple, intermediate and complex proton therapies as proposed in the CMS CY 2006 OPFS rule. We urge CMS to make the proposed rule its final rule for CY 2006.

This will ensure that the Nation's premier cancer treatment centers have the ability to provide cancer patients with this successful treatment.

Currently, over 46,000 cancer patients have been treated with protons in many institutions around the world, including three institutions currently providing proton beam therapy in the United States. Positive clinical results

800.842.8688 / fax 712.731.8654 / www.medtec.com
PO Box 320 / Orange City, Iowa 51041 / USA

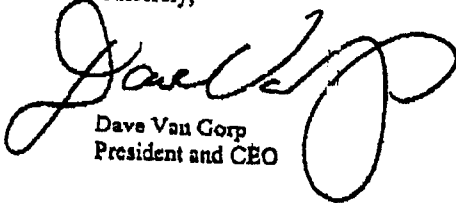
From these facilities have stimulated worldwide interest in the clinical applications of proton therapy and consequently numerous facilities are in the planning or construction phases

Proton beam therapy is in an early stage of clinical adoption. The required equipment is significantly more expensive to purchase and maintain than standard radiation treatment equipment. A typical proton beam therapy center requires between \$70-\$125 million and more than three years to develop. As a result, the number of sites establishing proton beam therapy centers has not kept pace with the clinical demand for the service. For those sites establishing centers, cost continues to be a major concern, which underscores the importance of maintaining adequate Medicare payment for the technology. It is critical that CMS OPPS continues to work with the providers of proton therapy to understand and analyze the data for classification and payment, as was clearly seen by the CY 2006 proposed rule, to ensure the economic viability of both existing facilities and those in various stages of construction and development.

Proton therapy is responsible for improving health outcomes, quality of life and our standard for cancer treatment. Appropriate payment rates for proton beam therapy will ensure this leading-edge cancer therapy is available to those we serve.

Thank you for your prompt attention to this critical issue.

Sincerely,



Dave Van Gorp
President and CEO

Submitter : Joseph K. Jachinowski

Date: 09/16/2005

Organization : IMPAC

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

8/7/05 IMPAC Letter to Hon. Mark B. McClellan, M.D., Ph.D.

CMS-1501-P-513-Attach-1.PDF



IMPAC Medical Systems, Inc.
www.impact.com

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F 650.428.0721

August 7, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 314 G
Washington, DC 20201

Re: Proton Beam Therapy Payment Classification

Dear Dr. McClellan:

In the Proposed Calendar Year (CY) 2006 Rule: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY'06 Payment Rates (CMS-1501-P), CMS proposed rule we note the following as it relates to proton therapy:

1. The proposed rule maintains separate classifications for simple, intermediate and complex proton therapies (CPT-4 codes 77520, 77522, 77523 and 77525, respectively).
2. CMS also proposes to move intermediate and complex proton therapies (CPT 77523 and 77525) from a New Technology APC (1511) into a clinical APC (0667).
3. Payment rates are proposed to be \$764.74 under APC 0664 for simple proton therapies (77520 and 77522) and \$914.92 under APC 0667 for intermediate and complex therapies (77523 and 77525).

Maintaining separate APC rates for proton therapies of varied complexity is necessary to differentiate between resource demands of different treatment levels.

The proposed rates more accurately reflect the significant capital demands associated with developing and high operating costs of running a proton therapy center.

Also, it should be noted that this technology is in the early stages of diffusion and as such the number of claims data should be monitored carefully, as it is expected to be modest for the next 2-3 years, with an outlook to supporting patient access to proton beam therapy.

We strongly support the classification and payment rates for simple, intermediate and complex proton therapies as proposed in the CMS CY 2006 OPFS rule. We urge CMS to make the proposed rule its final rule for CY 2006.

This will ensure that the Nation's premier cancer treatment centers have the ability to provide cancer patients with this successful treatment.

Currently, over 46,000 cancer patients have been treated with protons in many institutions around the world, including three institutions currently providing proton beam therapy in the United States. Positive clinical results from these facilities have stimulated worldwide interest in the clinical applications of proton therapy and consequently numerous facilities are in the planning or construction phases.

Proton beam therapy is in an early stage of clinical adoption. The required equipment is significantly more expensive to purchase and maintain than standard radiation treatment equipment. A typical proton beam therapy center requires between \$70-\$125 million and more than three years to develop. As a result, the number of sites establishing proton beam therapy centers has not kept pace with the clinical demand for the service. For those sites establishing centers, cost continues to be a major concern, which underscores the importance of maintaining adequate Medicare payment for the technology. It is critical that CMS OPFS continues to work with the providers of

proton therapy to understand and analyze the data for classification and payment, as was clearly seen by the CY 2006 proposed rule, to ensure the economic viability of both existing facilities and those in various stages of construction and development.

Proton therapy is responsible for improving health outcomes, quality of life and our standard for cancer treatment. Appropriate payment rates for proton beam therapy will ensure this leading-edge cancer therapy is available to those we serve.

Thank you for your prompt attention to this critical issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Joseph K. Jachinowski", with a long horizontal flourish extending to the right.

Joseph K. Jachinowski
President & CEO

Submitter : Dr. David Peura
Organization : American Gastroenterological Association
Category : Health Care Professional or Association

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-514-Attach-1.DOC



September 15, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates

Dear Doctor McClellan:

The American Gastroenterological Association (AGA) is the nation's oldest not-for-profit medical specialty society, and the largest society of gastroenterologists, representing more than 14,000 physicians and scientists who are involved in research, clinical practice, and education on disorders of the digestive system. The American Society for Gastrointestinal Endoscopy (ASGE) represents more than 8,000 physicians who specialize in the use of endoscopy to diagnose and treat gastrointestinal diseases and conditions.

The AGA and ASGE welcome the opportunity to comment on the proposed changes to the hospital outpatient prospective payment system for 2006.

Pass-Through Device Categories

We are pleased that CMS has addressed its policy of whether devices inserted through natural orifices should be eligible to qualify for "pass-through" payment under the hospital outpatient prospective payment system. CMS is to be commended for recognizing that a traditional definition of surgical incision limits access to innovative, less invasive technologies that can be inserted through an orifice. These technologies offer benefits for Medicare beneficiaries and avoidance of more invasive, costly surgery.

By way of implementation, CMS proposes to modify the current interpretation of regulation §419.66(b)(3) to consider devices pass-through eligible if inserted or implanted through a natural

or surgically-created orifice within the scope of surgically implanted devices, as well as those that are inserted or implanted through a surgically created incision. While this interpretation resolves the need to establish the existence of a traditional surgical incision to insert/implant a device through an orifice, we suggest that regulatory language be modified to institutionalize this change.

Recommendation:

We request consideration by CMS to change the regulation to read:

§419.66 (b)(3) The device is an integral and subordinate part of the service furnished, is used for one patient only, comes in contact with human tissue, and is implanted or inserted, through a natural or surgically created orifice or through a surgically created incision, whether or not the device remains with the patient when the patient is released from the hospital.

Device-Dependent APCs

We are concerned about the proposed reduction in APC 0384, GI stenting procedures, of 14.5% for 2006. This would also represent a cumulative reduction of 16.5% since CY 2004. The payment rate for this APC is clearly inadequate to cover the cost of the stents and the hospital's associated labor and overhead for these procedures.

As indicated by a number of presenters at the August APC Advisory Panel meeting, CMS is currently setting payment rates using claims where C codes were not reported. For device dependent APCs, there are substantial inconsistencies on the part of hospitals in the billing for the C code for the device and for the related procedure code. It is for this reason that CMS has mandated for 2005 billings that hospitals are required to report the C code for device dependent APCs along with the charge for the procedure. However, the 2005 claims data is not available for use in determining the 2006 HOPPS rates. For 2006, CMS is using data for 2004 claims when the billing of the C code was optional. An analysis of the data for claims assigned to APC 0384 indicates that the median costs of claims with C codes reported are substantially higher than the median cost for claims with the procedure code and a C code if one was reported.

CMS has decided to use all claims for gastrointestinal stent procedures that would otherwise meet its single claim standard regardless of whether a C code was reported. The reason for this decision was CMS' concern that for many device dependent APCs, using only claims for which a C code was reported might result in small number of claims used to calculate payment and/or the belief that these claims might not be representative of hospital costs. While this may or may not be true for other device dependent APCs, it is our judgment that this rationale does not apply to the Gastrointestinal stent procedures. First, there would be an adequate number of these claims to reliably determine median costs for this APC. Second, we think the resultant median costs would be a much more accurate representation of actual costs of providing the stent procedures which involve disposable devices that can cost up to \$1,900.

At the August APC Advisory Committee meeting, Boston Scientific, one of the major manufacturers of stents, presented this issue. The Committee recommended to CMS that it use only claims which included a C code in the calculation of median costs of APC 0384. We agree with this recommendation and urge that CMS adopt this change for the final rule.

However, a second recommendation of the APC Advisory Committee relating to this APC was for CMS to split the GI stent APC into two groupings: ERCP with stent placement and all other stent codes. The rationale for this recommendation apparently flows from the erroneous belief that the ERCP stent placement codes require substantially less time to perform because of the use of fluoroscopy. We disagree with the recommendation and urge that CMS leave APC 0384 intact for 2006. With regards to the distinction between ERCP and other stent placement procedures, we would note that procedures involving stenting of the gastrointestinal lumen require deployment of stents across a stenotic region. This is true for both stent placement in the biliary tree (ERCP) and stent placement elsewhere in the gastrointestinal tract. The area of stenosis is most typically caused by an end stage malignancy and frequently these patients have very limited treatment options. Irrespective of the location to be stented, similar techniques are employed to accomplish the procedure. Specifically, the narrowed region is approached endoscopically. Under continuous fluoroscopy monitoring contrast is injected to define the stenosis, a guidewire is placed across the region of narrowing under fluoroscopic visualization, a stent is placed across the narrowing, and then the stent is deployed. For all stenting procedures, fluoroscopy is an integral component of the service in that the physician cannot visualize the distal stent due to tumor stenosis (or position within the bile duct). Radiological monitoring is needed to insure that the ultimate position of the stent satisfactorily extends across the entire luminal stenosis.

For both biliary and non biliary stent placement, radioopaque contrast is injected across the luminal narrowing to verify the extent of narrowing and to assess for any fistulas. In most settings, this injection of contrast is performed with an ERCP type cannula, whether the tumor is within the esophagus, colon, bile duct or elsewhere. Similarly, the guidewires employed in stent placement are the same as those used for ERCP. Thus, stent placement in the biliary tree and elsewhere in the gastrointestinal tract requires similar equipment, supplies, techniques and fluoroscopic assistance. Therefore, we respectfully disagree with the Advisory Committee regarding their comments about the duration of these procedures. The selection bias inherent in this service affords a patient population enriched with elderly, cachexic and debilitated individuals who stand to gain some benefit when non surgical palliation of their malignant gastrointestinal obstruction occurs. Rather, we suggest that physician and fluoroscopy time for performance of stent placement is determined more by nuances arising from gaining access across the tumor, sedating the patient and fluoroscopic monitoring, rather than the inherent location of the malignancy.

Recommendation:

We encourage CMS to recompute the median cost of APC 0384 using claims with appropriately reported C codes as recommended by the APC Advisory Panel. As an alternative, we urge CMS to freeze payments rates for APC 0384 and other device-dependent APCs for 2006. This would only need to be a one-year temporary measure since rates set for 2007 will use 2005 claims where there is mandatory billing of C codes.

We also urge CMS not to adopt the recommendation of the APC Advisory Committee to split the GI stent APC into two groupings: ERCP with stent placement, and all other stent codes. We believe CMS will have much more accurate data on the costs of device dependent APCs in 2006 when use of C codes will be mandatory in the claims data used to construct the APC rates. It

would be preferable not to modify the APC assignment of the stent codes at this time until better data is available before considering any APC reassignment of these codes.

Addendum B - CPT Code 91035

In the 2006 proposed rule that was published in the July 25, 2005 *Federal Register*, CMS proposed to move CPT 91035 (Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation) from APC 1506 to APC 0361, *Level II Alimentary Tests*. We were concerned about the lack of clinical coherence with movement of this procedure to APC 0361 which would have resulted in a 52% payment decrease. We appreciate the agency's prompt and appropriate response for recognizing that the proposed APC change was an error; as per the August 26 *Federal Register* correction notice, CPT 91035 is proposed to remain in APC 1506 for 2006.

Recommendation:

We support retaining this CPT code 91035 in APC 1506 until better data is available before considering any APC reassignment of this procedure.

Interrupted Procedures

We wish to comment on the application of the proposed 50 percent reduction in payment for procedures reported with a 52 modifier. Our concern relates to the capsule endoscopy of the esophagus (PillCam ESO). We agree there is reduction in the professional component associated with this procedure if the ileum is not visualized. However, we disagree that there is absolutely no reduction in the resources incurred for the technical component or facility costs whether or not the ileum is visualized, and recommend that the proposed payment reduction not be applied on this procedure.

The manufacturer of this technology had requested a new technology APC for this procedure. Their application was denied on the grounds that the procedure could be adequately described by an existing code, namely, CPT Code 91110 with a 52 modifier. We would note that Code 91110 is defined as follows:

Gastrointestinal tract imaging, intraluminal (e.g. capsule endoscopy), esophagus through ileum, with physician interpretation and report.

(Append modifier 52 if the ileum is not visualized).

The rationale for the proposed 50 percent reduction in payment for procedures reported with a 52 modifier is based on the assumption that the resource costs are substantially diminished. This may well be true for a discontinued radiological service which seems to be the main focus of the proposal. However, we do not think the reduction in payment for a capsule endoscopy of the esophagus is appropriate or consistent with the HOPPS objective to pay appropriately based on the resources required to produce a service.

Certainly, it is consistent with the definition of code 91110 that there is a reduction in the professional component associated with the interpretation of the images when the gastrointestinal tract from the esophagus through the ileum is not completely visualized. This is because the physician has fewer images to interpret to obtain a diagnosis in those instances when only the esophagus is visualized. However, there is no comparable reduction in the resources required for the technical component or the facility costs covered by the APC rate for Code 91110 whether or

not the ileum is visualized. This is because the staff, equipment, overhead and, most importantly, supply costs associated with the disposable capsule camera, are identical for all capsule endoscopy procedures, whether only the esophagus or the upper gastrointestinal and small intestinal tract is visualized. As the costs for the technical component costs are essentially identical, this does not represent a "reduced service" from the standpoint of hospital resource costs.

Obviously the proposal to provide for a 50 percent reduction in payment for services for which a 52 modifier is appended is considerably broader than the capsule endoscopy procedure.


Recommendation:

If CMS, however, decides to proceed with this proposed policy in the final rule for radiobiology and other services not involving anesthesia, we strongly urge CMS not to apply this reduction to capsule endoscopy of the esophagus. This could be accomplished by a variety of actions including the following:

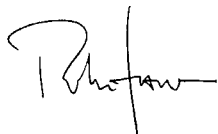
- Exempt hospitals from being required to report Code 91110 without a 52 modifier for capsule endoscopy of the esophagus or in other instances when the ileum is not visualized.
- If the decision is to require the use of the 52 modifier, establish an administrative exception so that intermediaries would not reduce payment under HOPPS in any situation where Code 91110-52 is reported. A reduction in payment would of course still be applicable for the professional component.
- Establish a temporary code to be used by hospitals to report the technical component of the capsule endoscopy of the esophagus procedure. The payment should be equal to the APC rate for Code 91110.

Thank you for consideration of our comments on the 2006 hospital outpatient prospective payment proposed rule. If we may provide any additional information on our comments, please contact Anne Marie Bicha, AGA Director of Regulatory Affairs at 301-654-2055, ext. 664 or abicha@gastro.org or Bernard Patashnik, ASGE, at 202-833-0007 or bpatashnik@aol.com.

Sincerely,



David A. Peura, MD
AGA President



Robert Hawes, MD
ASGE President

Submitter : Ms. Lee Grindheim

Date: 09/16/2005

Organization : NDO Surgical

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1501-P-515-Attach-1.DOC



115 High Street
Worcester, MA 02095
(508) 857-0961

Mark McClellan MD PhD
Administrator, Center for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. McClellan,

Included in the proposed updates to the Hospital Outpatient Payment System are proposed changes to Level II APC 0422. Currently included in APC 0422 is the Plicator procedure, indicated for the endoscopic treatment of symptomatic gastroesophageal reflux disease (GERD). The Plicator was first commercialized in the United States in April 2004. The following year, in April 2005, CMS assigned the Plicator procedure to HCPCS C9724 with placement into APC 0422. We are concerned that neither the current nor the proposed payment level for APC 0422 appropriately reflects costs incurred during the Plicator procedure.

An examination of the costs involved in performing the Plicator procedure suggests that its assignment to APC 0422 violates the two times rule. NDO Surgical understands that, given the recent nature of the Plicator APC assignment, CMS has been unable to incur claims for the Plicator. However, since the list price for the Plicator Procedure Kit (single-use) is \$1,795. We believe that an analysis involving the Plicator Procedure Kit list price is useful in calculating an appropriate payment level for the Plicator procedure:

HCPCS C9724 includes the cost of the Plicator Procedure Kit (\$1,795) as well as upper endoscopy (\$460, based on 2004 national average), for a total procedure cost of **\$2,255**. Also included in APC 0422 is CPT 43228, one of the most frequently invoked codes within APC 0422, presenting with a mean cost of approximately **\$1,000**. These data indicate a violation of the two times rule, evidenced by the cost of C9724 exceeding twice that of the least costly procedure within the same APC group. They also highlight the lack of cost homogeneity within APC 0422.

Additionally, the Plicator is a new technology recently introduced into clinical practice: its assignment to APC 0422 is not reflective of its new technology status. It may be more appropriate to consider establishment of a Level III APC which would more accurately reflect this new technology.

Thank you for this opportunity to present our views. We look forward to further discussions on this issue. We would request an opportunity to testify in any future meetings of the APC Advisory Panel.

Sincerely yours,

Lee Grindheim
Director, Reimbursement

NDO Surgical, Inc.

Attachment #515

Submitter : Julie Cantor-Weinberg
Organization : Guidant Corporation
Category : Device Industry

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

CMS-1501-P-518

Submitter : Mr. Scott Wolven

Date: 09/16/2005

Organization : Ethicon, Inc.

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-518-Attach-1.DOC

September 16, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates – "Pass Through Device Categories".

Dear Dr. McClellan:

Thank you for the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule for the Fiscal Year 2006 Outpatient Prospective Payment System. ETHICON, INC, a Johnson & Johnson Company, is a medical device company working in the areas of wound management, women's health and urology, cardiovascular surgery, and surgical wound closure. We strongly support the proposed modification in the way CMS will interpret the criterion that a device must be surgically inserted or implanted under §419.66(b)(3) of the regulations. This modification would allow CMS to consider eligible for pass through payment those items that are surgically inserted or implanted either through a natural orifice or a surgically created orifice. Proposed Changes to the Medicare Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates, Proposed Rule 70 Fed. Reg. 42721.

By including this proposed recommendation in the final rule, CMS will allow Medicare beneficiaries to benefit from new technologies that are used in a natural orifice, rather than the traditional method of requiring a scalpel or other sharp object to create a surgical opening. Potential benefits of surgery through a natural orifice are as follows: less pain, reduced blood loss, reduced scarring, decreased chance of infection and less injury to tissue. Because this method eliminates the need for a surgical opening (and subsequent closing), Medicare patients should have less post-operative pain, discomfort, and blood loss in most cases, since sutures, staples, and/or dressing would be unnecessary. Also, Medicare beneficiaries would have reduced scarring and decreased chance of infection since there will be the elimination of trauma to opening skin layers, from the epidermis to subcutaneous tissue. Finally, by reducing the need for an incision for a

surgical site, many Medicare patients will benefit from the elimination of any additional opening in the muscle tissue, which requires additional time to heal, as opposed to a natural orifice.

As the Proposed Rule makes clear, manufacturers would have to meet all of the other standards for establishing a new pass through device payment before a new technology would qualify. In the area of women's health, technologies that could qualify as a result of this modification regarding natural orifices could be inserted through the vagina and cervix and into the uterus to either ablate or reconfigure the uterine wall, thus eliminating endometriosis. Furthermore, a technology to detect or treat cervical cancer, which is inserted into the vagina to reach the cervix, should also qualify under this new proposed criterion. Therefore, Medicare beneficiaries would be allowed access to these types of future technologies, under the proposed pass through system changes.

In conclusion, we strongly support the modification of the definition of "surgically inserted or implanted" to include insertion or implantation through a "natural orifice" when establishing new pass through device categories. As a result of this change, Medicare beneficiaries will now have access to new invasive technologies and will benefit when undergoing surgery with these new technologies by the reduction of blood loss, quicker recovery time, less chance of infection risk, less pain, and reduced scarring/less injury to tissue layers.

We look forward to the published comments before the final rule is implemented on January 1, 2006.

Thank you for your review and consideration of these comments. If you have any questions, please feel free to contact me at 908-218-2358.

Sincerely,

Scott Wolven
Reimbursement Director
ETHICON, Inc.
Route 22 West
PO Box 151
Somerville, NJ 08876
908-218-2358



1740 Massachusetts Avenue
Boxborough, MA 01719
978-264-2004 (Phone)
978-268-5010 (Fax)

September 16, 2005

VIA ELECTRONIC SUBMISSION

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

**Re: Proposed Changes to the Hospital Outpatient Prospective Payment System and
Calendar Year 2006 Payment Rates [CMS-1501-P]**

Dear Dr. McClellan:

I am submitting these comments on behalf of Almyra, Inc., a small, research-driven portfolio of medical device companies developing innovative treatments for heart failure, diabetes, obesity, vascular disease, and stroke.

Almyra, Inc. recognizes that the Centers for Medicare and Medicaid Services (CMS) refines the Outpatient Prospective Payment System (OPPS) in an effort to increase payment accuracy for outpatient procedures and technologies. Almyra is encouraged by CMS' proposals to make much needed policy changes to the device pass-through payment eligibility criteria. Removing the requirement that a device must be implanted through a surgically created incision in order to qualify for pass-through payment will encourage use of less invasive technologies that have the potential to offer safer alternatives for Medicare beneficiaries. This policy change will ensure that minimally invasive procedures will be used in the hospital outpatient setting, and that such procedures will have the potential to receive appropriate payment. Most importantly, it will assist in providing patients with prompt access to the highest quality health care. Almyra also strongly endorses CMS's proposal to modify existing or previously existing pass-through device category criterion. This policy change will permit the establishment of pass-through payments for new device technologies that are not clearly described in an existing or previously existing category.

While we are appreciative of the proposed modifications to the pass-through payment eligibility criteria, we also want to highlight several areas of concern within the Calendar Year (CY) 2006 OPPS proposed rule. Almyra believes that without attention to and correction of these issues, Medicare beneficiaries will be adversely impacted by economic disincentives created by the following:

- Perpetuation of inappropriate payment levels based on flawed data, and
- Barriers to qualifying for New Technology APCs.

I. Inadequate Payment of APCs Based on Flawed Data

Almyra appreciates the agency's efforts to include multiple procedure claims data to calculate relative payment weights by using the "same date of service" and an expanded list of "bypass" codes in order to provide more single and "pseudo" single claims; however, additional revisions to the current methodology must be explored in order to ensure that CMS is basing payment on a substantial number of accurate and correctly coded hospital claims. Significant reductions in proposed 2006 payment rates for a number of device-related APCs are a direct result of the inaccurate capture of costs estimated from CMS' single and "pseudo" single procedure claim rate-setting methodology, as well as the use of incorrectly coded claims.

For device-dependent APCs, CMS has proposed to base the CY 2006 OPPS device-dependent APC medians on CY 2004 claims. However, in CY 2004, the use of device codes was optional, and thus data on medical devices has been more difficult to ascertain. Therefore, CMS has proposed to adjust median costs for device-dependent APCs to the greater of the median from claims data or 85 percent of the CY 2005 median used to set the payment rate in CY 2005 and not to impose a limit on the extent to which a median cost can increase.

Almyra appreciates CMS' recognition of the problem and for taking protection against large decreases in individual device APC payments, but allowing a 15% rate change from previous calendar years still perpetuates unpredictability in reimbursement and will lead to limited patient access to high-technology devices and procedures. As a small manufacturer, such dramatic fluctuations in reimbursement rates impact our ability to provide a stable purchasing environment for our customers. Since our companies typically have a single product, these substantial and unpredictable fluctuations cannot be offset by other products. In addition, we do not have flexibility in our pricing based on increasing cost of goods, inflation, and the more limited buying power of smaller companies. The value of innovation brought by small medical device companies will be lost if such companies continue to be subjected to payment fluctuations, and the patient will suffer the consequences.

Almyra believes it is important for CMS to use the best available data in setting rates, whether such data is generated internally by CMS or accepted from outside sources. In particular, external data may reduce the volatility in rates some APCs have

experienced in recent years. To date, CMS has not taken advantage of enough opportunities to improve payment adequacy based on external data.

The impact of charge compression on reimbursement rates is an example of the need for CMS consideration of multiple data sets, including external data. A system based on flat cost-to-charge ratio calculations often results in significant payment inequities. Manufacturers who believe their products are disadvantaged due to differential or disproportionate markups as a result of cost-to-charge ratio calculations should be allowed to present confidential data to CMS in support of their case for more adequate payment, and CMS should incorporate external independent and manufacturer data into the median cost calculations. Doing so would help CMS assess the validity of the rates derived directly from the claims data, and incorporate appropriate supplemental data into the median cost calculations setting the proposed APC weights.

We understand that CMS believes that the agency is able to determine reasonable rates with its own internal data, and that using external data is essentially an “exception methodology” that gives CMS more complete information to use in setting rates. However, use of external data should not just be an “exception methodology,” particularly where internal data based on the use of single or “pseudo” single procedure claims results in a very small number of claims on which to base payments. Often, data external to the agency is the more credible data source. In situations where manufacturers and hospitals can prove with external data that products are underpaid, CMS should make every effort to utilize this external data and make appropriate reimbursements to ensure patient access to new products and devices. Furthermore, accepting external data gives CMS important supplemental data sources without committing the agency to reliance on any particular data source when setting payment rates. Consequently, accepting external data can only benefit the agency’s reaching its goal of basing payments on the most accurate data.

Importantly, it is imperative that all external data used in rate setting be made private. If such data is available for public inspection, it will discourage viable data being presented to CMS and will impair the agency’s efforts to set payment rates based on the most accurate information.

Without adequate assurances of confidentiality, manufacturers and hospitals will be unwilling to release to CMS proprietary information that could be useful to competitors. In addition, many hospital purchasing contracts contain mutual non-disclosure clauses that would be breached if acquisition cost data were publicly released, potentially exposing hospitals or manufacturers to liability.

- *Almyra recommends that CMS develop alternative methodologies to capture both single and multiple procedure claims. Additional data will increase the likelihood of stable APC payments in the future.*
- *Almyra supports a limit on reductions for all APCs by imposing a reimbursement floor of 100 percent of the 2005 rates all device-related APCs.*

- *Almyra encourages the agency to expand its practice of considering external data beyond its current practice of considering it "exception methodology"*
- *CMS should agree to hold external data confidential and to protect this information from public disclosure.*

II. New Technology APCs

CMS is proposing to require that an application for a New Technology APC be submitted to the AMA's CPT Editorial Panel before CMS accepts a New Technology APC application for review. A copy of the submitted CPT application will have to be filed with CMS as part of the application for a New Technology APC assignment under the OPPS, along with the AMA's letter acknowledging or accepting the coding application.

The CPT process is under the purview of the AMA, not the public or the manufacturer, and therefore it is inappropriate to link application for a New Technology APC to applying for a new CPT code. First, there are only three submission deadlines per year for CPT applications, and these do not coordinate with the quarterly schedule for filing New Tech APC applications, potentially resulting in tremendous delays. Second, tying New Tech APC assignment to submission of a CPT application assumes that the manufacturer submits and controls the path of CPT applications. While it is possible for manufacturers to file a CPT application to the AMA, traditionally the AMA has discouraged this practice and medical specialty societies have been slow to support applications that are not vetted through them. Manufacturers may work with the specialty societies to support an application and encourage one to be filed; traditionally the appropriate medical specialty society carries the application forward through the process. In many cases, the specialty society writes the application or takes an application draft through an internal review process, where it is finalized before being officially submitted. Further, it is not unusual for a specialty society to hold an application (i.e. not formally accept it) depending on the internal workload or competing CPT applications being considered internally by that specialty society.

In reality, there is no consistency in the process for submitting a CPT application or in how it is processed internally through the various specialty societies that is necessary to assure consistent and predictable access to the New Technology APC opportunity across all therapeutic specialties, especially in a federal program. In addition, the AMA, as a private agency, is not bound by any timelines for processing applications and acknowledging them in writing. When the manufacturer is only party to submitting the application (because the specialty society submits the application and/or because multiple companies may be involved in a single application) the manufacturer may not be the recipient of a letter indicating that the application is in the system. All of these factors in addition to the misaligned application schedule will create further delays in new technologies being eligible to be applied for a New Technology APC.

It is important to note that the specialty societies and AMA's primary goal in CPT is to provide a vehicle for physician payment from both public and private payers through

the establishment of a relative values that reflect the work, malpractice risk, and overhead for the physician and the physician practice that delivers the service. Since the true purpose of CPT does not align with the goals of the OPPTS as a Medicare specific payment system, CMS should consider developing an alternative advisory committee of physicians and medical experts to assist in the review of New Technology APC applications.

Although CMS has proposed requiring manufacturers to merely file a CPT application (and not necessarily to obtain a CPT code), applying for a CPT code could have significant negative consequences that will impact access to the new technologies for which the New Technology APC is designed to provide access. For example, Medicare Carriers and Intermediaries have been releasing draft local coverage determinations that *categorically* deny payment for current and future Category III CPT codes. Therefore, submission of a coding application might lead to assignment of a Category III CPT code, resulting in automatic non-coverage of a device, and therefore, no payment. In addition, this unilateral non-payment policy could potentially prohibit reimbursements to physicians for their services related to use of the technology. Lastly, many private payers deny or cannot operationally accept Category III codes. CMS should not require manufacturers to engage in a process where the result could be a Category III code, a determination that may have negative ramifications for coverage by the Medicare program and/or by private payers, in order to apply for a New Technology APC. Many manufacturers will be unwilling to file New Technology APC applications because of this risk to provider reimbursement. Moreover, the consequences of this policy would be contrary to Congressional intent that New Technology APCs expedite beneficiary access to new technologies. In addition, it will increase the use of unspecified codes that will have a negative impact on the OPPTS data set by not providing service specific information that will contribute to appropriate APC assignment in the future.

Finally, Almyra strongly believes it is inappropriate to tie decisions about how a public program is going to reimburse new technologies to a privately run process that is not subject to public input or required to operate in the public domain. CMS leadership and staff has stated publicly on many occasions that it does not control CPT, and that decisions regarding CPT coding decisions are not within the agency's purview. The CPT application process as established by the AMA does not provide any opportunity for public comment or review of its decision making process. The federal government has historically promoted a policy of transparency, as seen in the Administrative Procedure Act (APA) and the Federal Advisory Committee Act (FACA). Almyra thinks that tying New Tech applications to the closed CPT application process at a minimum violates the spirit of federal transparency standards and requirements. The federal government should not require participation in an application process that allows no public review or recourse when establishing reimbursement under a federally-run and federally-funded program. CMS has been able to make decisions with regard to New Technology applications in the past without requiring an application for a CPT code.

- *Almyra believes this proposed new requirement to require a CPT code application to be filed in order to qualify for filing a New Technology APC application is an inappropriate use of a privately run program whose sole intent is not to serve as the payment system for the federally run Medicare Hospital Outpatient Prospective Payment System in order to introduce physician representation into the decision-making process for this federal payment system.*
- *Almyra suggests that CMS consider convening an independent or alternative group of medical experts that operates solely for the purpose of reviewing New Technology APC applications and assisting CMS make decisions specific to the Outpatient Prospective Payment System, as necessary, to assure that Medicare beneficiaries continue to have expeditious access to new and innovative technologies.*

III. Conclusion

Thank you for your consideration of these comments.

Sincerely,

Jo Ellen Slurzberg
Vice President, Reimbursement and Health Policy



1740 Massachusetts Avenue
Boxborough, MA 01719
978-264-2004 (Phone)
978-268-5010 (Fax)

September 16, 2005

VIA ELECTRONIC SUBMISSION

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 445-G, Hubert H. Humphrey Building
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III. Conclusion

Thank you for your consideration of these comments.

Sincerely,

Jo Ellen Slurzberg
Vice President, Reimbursement and Health Policy

CMS-1501-P-520

Submitter : Ms. Karen Ryan

Date: 09/16/2005

Organization : Geisinger Health System

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Please see attached document from Geisinger Health System, Danville, Pa regarding comments on CMS-1501-P "Proposed changes to Medicare outpatient payment system for CY 2006"

CMS-1501-P-520-Attach-1.DOC

Dispensing fees will vary significantly in each hospital due to variances in overhead and handling fees incurred. How is a legitimate payment rate calculated when comparing clinics to hospitals when hospitals incur much greater overhead costs? In addition, in attempting to cover the costs of overhead and handling fees, will the payments reflect the real costs incurred due to new regulations in USP Chapter 797 mandating procedures for "Clean Rooms" which would affect IV prep of all chemo drugs.

How will CMS compensate differently for the same drug that is purchased in a reconstituted form and have much greater acquisition costs than the same drug that is purchased as a dry freeze powder and prepared by the hospital? Will CMS expand the HCPC codes to account for these different costs as was done recently with lyophilized and non-lyophilized Immune Globulin? There are also cost differences associated with ready-to-use liquids versus a powder that needs to be prepared.

This proposal requires more research and consideration in order to reduce the administrative burden that will be required of hospital staff and adequately capture all overhead and handling costs incurred.

Because of these numerous issues and the clinical complexity in adopting this method of reimbursing providers for pharmacy overhead cost, GHS supports the payment for pharmacy overhead costs based on the additional 2% of ASP added to each APC drug payment. This method simplifies the payment mechanism, while still meeting the requirements of Pub. L. 108-173.

IV. Multiple Diagnostic Imaging Procedures

GHS does not support the CMS proposal to reduce the second and subsequent payments for radiology procedures performed within the same "Family" and during the same session. This proposal represents an additional reduction in overall reimbursement to providers from the Medicare system.

The modalities in GHS radiology departments that are affected by this proposal provide services to a large number of patients each day. Their work schedules will often have multiple studies done of the same area of the body. A typical daily work list in our ultrasound department could include as many as 4 out of 32 patients having two studies of the same area, transvaginal vs. transabdominal pelvic ultrasounds. This also holds true throughout our CAT scan and MRI departments.

In reviewing our radiology practice we do recognize that there could be some technical and administrative efficiencies gained; however, we do not feel that the technical efficiency gained on these studies would be as great as 50%, but rather around 25% to 30%. These efficiencies, however should have already been considered in the payment level of these procedures.

As such, we do not support the CMS proposal to reduce certain subsequent radiology procedures by 50% and encourage CMS to maintain the existing payment policy.

V. Non-Pass Through Payments Proposed Payment Policy for Radiopharmaceutical Agents

GHS does not support Medicare's proposal to begin collecting ASP data on radiopharmaceutical agents with the intention of converting them to an ASP-based payment system beginning in CY 2007. Since the inception of the payment program, Medicare has not utilized the resources that are available to it, such as the Society of Nuclear Medicine, for accurate data collection and consultative purposes.

Proposed Medicare Outpatient Changes for FY 2006

Page 5

failure, adverse reactions to the surgical intervention, excessive bleeding, etc. Because each case is different, and can be terminated at various points during the procedure, it is difficult to estimate the degree to which hospitals experience cost savings in these situations.

APC payments for procedures include payment for preoperative services, anesthesia services, the actual procedure, supplies, and postoperative care. In cases of termination, preoperative services, anesthesia services, supplies, and postoperative care still need to be provided, therefore we believe any cost savings in those areas would be minimal, if any. In addition, time in recovery may be even longer depending on the type and amount of drugs given to the patient. Cost savings on the actual procedure would again depend on each individual case.

The current proposal is merely speculative in nature. GHS recommends that CMS conduct a more extensive study to determine potential cost savings to hospitals prior to implementing a payment reduction. We agree with the APC panel's recommendation that CMS continue to pay 100% of the APC payment in these situations.

Thank you for the opportunity to comment on these proposed regulations.

Sincerely,

Karen Ryan

Karen Ryan
Director, Hospital Reimbursement
Geisinger Health System
Danville, PA

KR/vj

CMS-1501-P-521

Submitter : Mr. Ashok Chainani
Organization : Talecris Biotherapeutics
Category : Drug Industry

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comments to Proposed Changes (CMS-1501-P) to HOPPS & Calendar Year 2006 Payment Rates (July 25, Fed. Reg) from Talecris Biotherapeutics.

CMS-1501-P-521-Attach-1.DOC

September 16, 2005

SUBMITTED VIA ELECTRONIC TRANSMISSION TO

<http://www.cms.hhs.gov/regulations/ecomments>

Mark McClellan, MD, PhD
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
200 Independence Avenue, S.W.
Hubert H. Humphrey Building
Washington, D.C. 20201

Re: Comments to Proposed Changes (**CMS-1501-P**) to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates published in the Federal register on July 25, 2005.

Dear Administrator McClellan:

On behalf of Talecris Biotherapeutics we appreciate this opportunity to comment on the proposed rule concerning the 2006 Hospital Outpatient Prospective Payment System ("HOPPS") rates, published in the Federal Register on July 25th, 2005 ("Proposed Rule").¹

Talecris Overview

Talecris is a new company focusing on development and delivery of plasma-based therapeutics to treat serious, life-threatening and rare disorders. In 2005, we acquired the contributed assets of Bayer Biological Products' plasma business, including the immune globulin intravenous (IGIV) product Gamunex®, Immune Globulin Intravenous (Human), 10% - Caprylate / Chromatography Purified Gamunex® supplies a broad spectrum of antibodies for the prevention or attenuation of a wide variety of infectious diseases and treats many immune deficiencies.

Proposed Payment Could Have Significant Adverse Impact on Patient Access to IGIV Treatment

The proposed rule would reduce payment for lyophilized IGIV by 50 percent and payment for liquid (non-lyophilized) IGIV by 28 percent under the ASP+8% methodology. Given the dynamics of the IGIV marketplace described below, we believe that the HOPPS rule if promulgated as proposed will have a serious impact on patient access to this lifesaving therapy

In 2005, hospital outpatient departments have been a "safety net" for IGIV patients who have lost access to physician-office treatment. Some doctors cannot purchase the product at anywhere near the Part B reimbursement rate and, as a result, have

¹ Fed. Reg. Vol. 70, No.141

stopped infusing IGIV to Medicare beneficiaries. (See e.g. "Medicare Changes Force Scrambling for Drugs" reported by the Associated Press on June 13, 2004 and published in the *New York Times* on June 14, 2004.) To the extent that hospitals are able to acquire the quantity and type of IGIV needed by these patients, hospitals have been ready, willing and able to provide IGIV infusion services because the 2005 reimbursement is typically more than their actual acquisition cost.

Our market research shows that hospitals are no more likely to cover their acquisition cost with ASP+8% reimbursement than physicians have been able to do at ASP+6%. As you know, ASP is linked to the manufacturer's selling price, but providers are subject to middle-market forces that can increase the price well beyond ASP. Such is the case with IGIV, where providers routinely report paying significantly more than ASP + 6% or 8%.

If hospital payment is reduced to essentially the same reimbursement that now exists for the physician office, and hospitals elect to not treat rather than to lose money, Medicare patients will have nowhere to go despite the fact that sufficient IGIV product is available in the supply chain.

To prevent what would be a crisis in care for these patients, CMS should make an adjustment for IGIV HOPPS payment and related services.

Recommendations for Adequate Payment for IGIV Products and Infusions

1. Interim Add-On Payment

The PPTA (Plasma Protein Therapeutics Association) has commissioned Lewin Group to study market-based pricing for IGIV. That pilot study is expected to be completed soon and in the short-term, based on this study of hospital outpatient departments, Lewin will develop a "proxy figure" that would allow CMS to establish an interim "add-on" to the proposed ASP + 8% so that the reimbursement for IGIV to the hospital outpatient setting would more accurately reflect the cost to patients. This "proxy" add-on could be used until a long-term in-depth analysis is complete.

2. Permanent Add-On Payment

A more detailed study by Lewin will determine the magnitude of an appropriate "add-on" payment for IVIG, as well as the relative distribution of costs across product acquisition, handling, and administration by December 2005. These could be used to develop an "add-on" payment for IGIV. The PPTA in their comments provided details on this study. We support this approach.

3. Delay Application of ASP Methodology to IGIV:

If the above two solutions are not acceptable to CMS, we suggest delaying the application of the new ASP payment methodology to IGIV to avoid adverse consequences on patient access.

4. Dampening Provision:

If # 3 is not acceptable, as a much less satisfactory alternative to the above CMS could apply the 15% dampening provision to the HOPPS IVIG payment for determining the 2006 payment rate.

5. Additional Steps to Better Match Reimbursement to Cost

A. Classification of IGIV As a Biologic Response Modifier

To equalize payment to match intensity/complexity of patient management CMS needs to consider changing the classification of IGIV as a biologic response modifier (BRM). That will then allow appropriate payment and adequately reimburse providers (physicians and nurses) for the complex patient management similar to resource utilization and complexity to management of cancer patients. Once classified as a BRM allow the use of chemotherapy administration codes G0359 for the first hour and G0360 for subsequent administration.

B. More Granular Coding to Reflect Clinically Significant Differences in IGIV Products

The PPTA in their comments to CMS on September 9th detailed the differences in IGIV brands. We strongly agree with their assessment and therefore suggest CMS issue separate for each IGIV product and base reimbursement on the outcomes from the various therapies as some have the potential to reduce other costs associated with the IGIV administration, as seen in our own (unpublished) study comparing our two liquid formulations of IGIV.

CONCLUSION

Since the implementation of the MMA and ASP+6% for physician offices, there has been an increasing trend of patient being sent to hospitals for treatment with IGIV because inadequate reimbursement in the physician office setting results in some patients losing that treatment option.. If reimbursement to hospitals declines to the same level where the cost of acquisition of IGIV is higher than the reimbursement, we are bound to see access issues intensify in both sites of service. CMS should proactively prevent that from happening by adopting the changes recommended in these comments.

We look forward to working with you and your staffs toward that goal.

Respectfully submitted,

Ashok A. Chainani (Signed)

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Submitter : M. Mitchell Latinkic

Date: 09/16/2005

Organization : M.D. Anderson Cancer Center

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

8/24/05 Letter from M. Mitchell Latinkic (Division Administrator, Division of Radiation Oncology - The University of Texas, M.D. Anderson Cancer Center) and Allan Thornton, M.D. (Medical Director, Midwest Proton Radiotherapy Institute at Indiana University) to Hon. Mark B. McClellan, M.D.; re Proton Beam Therapy

CMS-1501-P-522-Attach-1.PDF

PROTON THERAPY CONSORTIA

*Loma Linda University Medical Center • Massachusetts General Hospital • The University of Texas M.D.
Anderson Cancer Center • University of Florida Health Science Center • The Midwest Proton
Radiotherapy Institute at Indiana University
New York Presbyterian Hospital • University of Pennsylvania Medical Center/The Children's Hospital of
Philadelphia • Arthur G. James Cancer Hospital/Ohio State University*

August 24, 2005

Honorable Mark B. McClellan, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8018

RE: CMS-1501-P, Proton Beam Therapy

Dear Dr. McClellan:

The Proton Therapy Consortia ("Consortia") is pleased to submit these comments on the proposed rule entitled *Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates*, CMS-1501-P.

We thank you and your very capable CMS staff for your interest and continuing efforts on behalf of proton beam therapy. We fully understand and appreciate the complexities of the hospital outpatient payment system in developing the proposed rule.

We are writing in support of CMS's proposal to move intermediate and complex proton beam therapy from a New Technology APC (1510) to a clinical APC (0667), with a payment rate of \$918.97.

ABOUT THE PROTON THERAPY CONSORTIA

The Proton Therapy Consortia ("Consortia") consists of a group of premier cancer treatment centers in the United States that offer, or are in process of building the capacity to offer, proton beam therapy. Members of the Consortia include seven institutions. Those currently providing proton beam therapy in the United States are:

- Loma Linda University Medical Center (in clinical operation since October 1990);
- Massachusetts General Hospital (in clinical operation since November 2001);
- Midwest Proton Radiotherapy Institute at Indiana University (in clinical operation since February 2004).

The other four members are centers that are in some stage of planning or construction and include:

PROTON THERAPY CONSORTIA

- The University of Texas M. D. Anderson Cancer Center (start of operations, early 2006);
- The University of Florida Health Science Center (start of operations, mid 2006);
- University of Pennsylvania Medical Center /The Children's Hospital of Philadelphia (planning stage); and
- Arthur G. James Cancer Hospital/Ohio State University (planning stage).

COMMENT LETTER OVERVIEW

In the remainder of this Comment Letter, we provide the following:

- (1) an overview of the issue on which we are commenting,
- (2) a summary of the clinical benefits of proton therapy,
- (3) summary of resource demands related to simple, intermediate and complex therapies,
- (4) efforts that will be undertaken in the future to ensure that the hospital outpatient claims data accurately reflect the cost of proton therapy as the technology diffuses in the market, and

Overview of the Issue to which our Comments are Directed:

CMS states on page 124 of the 2006 proposed rule that:

Our examination of the CY 2004 claims data revealed a second year of stable, albeit modest, number of claims on which to set the CY 2006 payment rates for CPT 77523 and 77525. However, unlike the median of \$690.45 for CY 2005 Level II proton beam radiation therapy clinical APC containing 77523 and 77525 derived from the CY 2003 claims data, the median for a comparable Level II proton beam radiation therapy clinical APC is \$934.46 derived from the CY 2004 claims data.

The CY 2005 claims totaling 263 were used to set the CY 2006 proposed rule, which reflects an increase of approximately 12.9% from the CY 2004 claims.

The proposed rule goes on to note that:

This more recent median appears to more accurately reflect the significant capital expense and high operating costs of a proton beam therapy facility, and support patient access to proton beam therapy. Therefore, we are proposing to move CPT codes 77523 and 77525 from New Technology APC 1510 to clinical APC 0667 (Level II proton beam radiation therapy) based on a median cost of \$934.56 for CY 2006.

We agree with the CMS and strongly urge that the CY 2006 proposed rule, as noted in Exhibit 1 below, be reflected in the final rule.

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Exhibit 1: Proposed Changes in APC Assignment and Payment Rates for Proton Therapy

CPT Code	Description	2005		2006 Proposed	
		APC	Payment Rate*	APC	Payment Rate*
77520	Proton treatment, simple w/o compensators	0664	\$566.99	0664	\$768.13
77522	Proton treatment, simple with compensators	0664	\$566.99	0664	\$768.13
77523	Proton treatment, intermediate	1510	\$850.00	0667	\$918.97
77525	Proton treatment, complex	1510	\$850.00	0667	\$918.97

**Reflects the national average payment. Actual payments will vary. Payment rate includes the patient coinsurance amount.*

Clinical Benefits of Proton Therapy:

The clinical benefits of proton beam therapy over conventional radiation therapy can be summarized as follows:

1. Increased tumor control, due to proton beam therapy's ability to increase the radiation dose administered to the targeted tumor;
2. Reduced occurrence of treatment-related tissue damage and other side effects, because of the precision of dose delivery and the resulting limited amount of radiation delivered to healthy tissues adjacent to the tumor site;
3. Decreased normal tissue toxicity when radiation and chemotherapy are given simultaneously;
4. Increased long-term disease-free survival rates for many tumors, due to proton beam therapy's superior local tumor control; and
5. Potential increase in the daily dose of radiation being delivered to the tumor thereby reducing the number of daily patient treatments.

Proton beam therapy has a demonstrated record of providing superior local tumor control. An appropriate payment rate for proton therapy is important to the development of proton beam therapy centers and should have the long-term effect of reducing health care costs afforded by this therapy.

Current APC Rates Adequately Differentiate Between Resource Demands of Different Treatment Levels:

The four proton beam therapy CPT codes (77520, 77522, 77523 and 77525) are defined and categorized according to resource utilization and the complexity of the treatment delivery requirements. A cost relationship exists between the four proton treatment CPT codes (simple – with and without compensation, intermediate and complex). Each code reflects the actual resources utilized during treatment delivery.

PROTON THERAPY CONSORTIA

These resources include: capital investment in equipment; replacement of obsolete or improved technology; cost of new technology; maintenance costs; additional personnel costs related to equipment operations; and, additional time required to deliver the appropriate course of therapy.

A simple patient treatment episode may take as little as 10 minutes on a daily basis while intermediate and complex therapy may take between 45 minutes to 60 minutes on a daily basis. The tumor size, shape, dose and association with other anatomic structures determine the duration of proton therapy, the time spent in the treatment room, and the technology/resources required for treatment. The time difference alone for intermediate and complex proton therapy is generally three to four times the time spent for simple proton treatment.

The significant difference in resource consumption and complexity between the simple and the intermediate/complex procedures as identified in the CPT codes is more reasonably captured in the proposed CY 2006 CMS OPPS payment rates.

Capital Resources:

A typical proton beam therapy center will consist of 2-6 treatment rooms of which most include rotating gantry structures. Each gantry weighs in excess of 100 tons and is capable of rotating 360 degrees around the patient so as to deliver the proton beam therapy with sub-millimeter precision. Each facility requires up to \$125 million and more than three years to develop. A proton beam therapy center can be open 16 hours each day and employs radiation oncologists, physicists, nurses, medical dosimetrists, therapists and technical personnel.

For comparison, a typical conventional radiation therapy center, with 1-2 treatment vaults to accommodate a linear accelerator, gamma knife or cyber knife, will take 8-12 months to construct and prepare for clinical use. Capital requirements are between \$4 and \$6 million. Operating ramp-up for a conventional radiation therapy facility will usually require 2-3 months, or less in some instances.

Future Accuracy of Claims Data for Proton Therapy:

Loma Linda University Medical Center and Massachusetts General Hospital have created proton therapy-specific cost centers in their Medicare cost reports, in recognition of the high proton therapy capital and operating costs. This cost data will appear in the cost data used by the CMS to set the CY 2007 OPPS payment rates.

However, it should be noted that Loma Linda University Medical Center's fiscal intermediary has not permitted certain material operating costs to be allocated directly to the proton therapy-specific cost centers in their Medicare report. Most noteworthy of these being depreciation expense, associated with the proton therapy building and equipment, and the proton therapy equipment repairs and maintenance expense. These items are under appeal but have the impact of reducing the cost of proton therapy being reported by Loma Linda University Medical Center to CMS. This remains as a concern.

The Consortia is committed to working with CMS to ensure that the hospital outpatient claims data for proton therapy are as accurate as possible. We look forward to an ongoing dialogue with CMS on these important issues, and we appreciate the opportunity to submit and discuss these comments with CMS.

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CONCLUSION

Currently, over 40,000 patients have been treated with protons in many institutions around the world. In spite of the proven effectiveness of proton beam therapy, the development of a clinical proton beam therapy center is still challenged with the complexity, size and cost of the necessary equipment and physical facility.

Proton beam therapy is in an early stage of clinical adoption and the required equipment is significantly more expensive to purchase and maintain than standard radiation treatment equipment, which is a relatively more mature technology and has a large installed base and widespread clinical acceptance.

We strongly agree with CMS's CY 2006 proposed payment rule for proton beam therapy and urge that it be repeated in the final rule.

As always, please feel free to call upon us at (713) 563-2314 if you have any questions or if we can provide further data that can assist CMS's rule making.

Sincerely,



M. Mitchell Latinkic
Division Administrator
Division of Radiation Oncology
The University of Texas
M. D. Anderson Cancer Center



Allan Thornton, M.D.
Medical Director
Midwest Proton Radiotherapy Institute
at Indiana University

Attachments:

- (1) Letters to CMS in Support of Consortia
 - (a) Congress
 - (b) Vendors
 - (c) Medical Specialty Societies

Submitter : M. Mitchell Latinkic
Organization : M.D. Anderson Cancer Center
Category : Health Care Provider/Association

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

7/1/05 Letter from Rep. Jerry Lewis (R-CA) to Hon. Mark B. McClellan, M.D., Ph.D.; re Proton Beam Therapy.

7/26/05 Response Letter from Herb B. Kuhn (Director, Center for Medicare Management) to Rep. Jerry Lewis (R-CA)

CMS-1501-P-523-Attach-1.PDF

Submitter : Mr. Mark Leahey
Organization : Medical Device Manufacturers Association
Category : Device Association

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1501-P-524-Attach-1.PDF



MEDICAL DEVICE MANUFACTURERS ASSOCIATION
Innovation Today For Better Health Care Tomorrow

September 15, 2005

VIA ELECTRONIC SUBMISSION

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

**Re: Proposed Changes to the Hospital Outpatient Prospective Payment System and
Calendar Year 2006 Payment Rates [CMS-1501-P]**

Dear Dr. McClellan:

I am submitting these comments of behalf of the Medical Device Manufacturers Association (MDMA), a national trade association representing over 200 innovative medical device companies. Our mission is to ensure that patients have access to the latest advancements in medical technology, most of which are developed by small, research-driven medical device companies.

MDMA recognizes that the Centers for Medicare and Medicaid Services (CMS) refines the Outpatient Prospective Payment System (OPPS) in an effort to increase payment accuracy for outpatient procedures and technologies. Part of that process is to determine proper reimbursement for technological advances in health care devices and patient treatment. Reimbursement policies should not discourage new scientific breakthroughs that allow procedures to be performed faster, more accurately, and with less invasive approaches that minimize risk and recovery times. Therefore, MDMA is encouraged by CMS's proposals to make important and needed policy changes to the device pass-through payment eligibility criteria. Specifically, MDMA strongly supports CMS's proposal to remove the requirement that a device must be implanted through a surgically created incision in order to qualify for pass-through payment. Using existing body openings rather than creating surgical incisions can reduce the rate of complications, shorten recovery times, and decrease inconvenience and pain for patients. This policy change will ensure that minimally invasive procedures will be used in the hospital outpatient setting, and that such procedures will receive appropriate payment. Most importantly, it will assist in providing patients with prompt access to the highest quality health care.

MDMA also strongly endorses CMS's proposal to modify existing or previously existing pass-through device category criterion. This important policy change will permit the establishment of pass-through payments for new device technologies that provide a substantial clinical improvement for Medicare patients and which are not clearly described in an existing or previously existing category.

While MDMA is appreciative of the proposed modifications to the pass-through payment eligibility criteria, we also want to highlight several areas of ongoing concern within the Calendar Year (CY) 2006 OPPS proposed rule. Our member companies believe that without attention to and correction of these issues, Medicare beneficiaries will be unable to access innovative technologies due to economic disincentives created by the following:

- Volatility in OPPS payment rates;
- Perpetuation of inappropriate payment levels based on flawed data; and
- Barriers to qualifying for pass-through and new technology APCs.

I. Volatility in Medicare payment rates

Recent volatility in Medicare payment rates has been devastating for many device companies. The lack of predictability makes it difficult for manufacturers, both large and small, to market and sell their products to health care providers. In particular, fluctuations in product reimbursement threaten the very existence of smaller, entrepreneurial companies which invent technologies that represent important advances in patient care.

Several of our member companies' products are currently being adversely affected by significant reimbursement volatility:

- Spinal cord stimulation laminectomy electrode implant procedures were linked to APC 0225 in 2005 with a reimbursement rate of \$11,996.03; however, in the proposed rule they are linked to APC 0040 at a reimbursement rate of \$3,283.43. This represents a 72.6% reduction in one year. Therefore, MDMA recommends that CMS adopt the APC Advisory Panel's recommendation to reconfigure neurostimulation electrode implantation APCs by creating three distinct APC groups to describe percutaneous implantation (Level I); laminectomy or incision for implantation (Level II); and cranial electrode implantation (Level III). This reconfiguration will greatly improve the clinical and cost congruence of these procedure groupings and for laminectomy electrode implant procedures specifically. The proposal will also eliminate the violation of the "two-times rule" if laminectomy electrode implant procedures were to stay grouped to APC 0040.
- Another example of payment volatility involves brachytherapy APCs. Specifically, in the 2006 proposed rule, CMS has proposed a reduction in payment levels for all brachytherapy APCs (312, 313 and 651). MDMA has concerns over the accuracy of CMS' brachytherapy data, as claims that had both the brachytherapy procedure and a

brachytherapy source “C” code revealed median costs that were 9% to 34% higher than the average all single-procedure claims for the APC. This suggests that more appropriate and accurate payment rates for brachytherapy APCs could be achieved through use of a correct coding screen. Such a system would be similar conceptually to the screens CMS has applied in the past to “device-dependent” APCs. *MDMA recommends that CMS re-establish efforts to employ only “correctly coded” claims for rate-setting purposes, where each brachytherapy procedure claim would contain an appropriate brachytherapy source “C” code(s). Further, CMS should provide more education to hospitals regarding the importance of accurate coding, including brachytherapy sources and related devices.*

- Further, CMS acknowledges in the proposed rule that a payment reduction of more than 15% from the 2005 HOPPS payment rate might be problematic for hospitals that provide those services. Brachytherapy APC 651 has a proposed reduction of 42.3%. We are highly concerned that this considerable payment reduction may affect access to this minimally invasive cancer therapy, particularly since this therapy has a lower incidence of serious complications such as impotence and urinary incontinence. *MDMA recommends that CMS use “correctly coded” claims to determine the median cost of APC 651, and if the 2006 final payment rate is reduced by more than 15 percent of the current 2005 payment, that CMS apply the “device-dependent” or similar adjustment factor to APC 651.*

II. APC Relative Weights

MDMA appreciates the agency’s efforts to include multiple procedure claims data to calculate relative payment weights by using the “same date of service” and an expanded list of “bypass” codes in order to provide more single and “pseudo” single claims; however, additional revisions to the current methodology must be explored in order to ensure that CMS is basing payment on a substantial number of accurate hospital claims.

Significant reductions in proposed 2006 payment rates for a number of device-related APCs are a direct result of the inaccurate capture of costs estimated from CMS’ single and “pseudo” single procedure claim rate-setting methodology. This is particularly problematic for procedures routinely performed in conjunction with other procedures (e.g., brachytherapy) whose costs would always be reported on multiple procedure claims but are not currently being captured under single claims methodology. APC 651 *complex interstitial radiation source application* contains one procedure code CPT 77778, which had a total of 11,963 claims; however, CMS utilized less than 3% of those claims for rate-setting purposes. Similarly, CMS utilized only 2% of hospital claims for non-coronary intravascular ultrasound, initial vessel (CPT 37250), which as an adjunctive procedure is always reported on multiple procedure claims. *MDMA recommends that CMS develop alternative methodologies to capture both single and multiple procedure claims. Additional data will increase the likelihood of stable APC payments in the future.*

III. Stabilize Rates for Devices

For device-dependent APCs, CMS has proposed to base the CY 2006 OPPS device-dependent APC medians on CY 2004 claims. However, in CY 2004, the use of device codes was optional, and thus data on medical devices has been more difficult to ascertain. Therefore, CMS has proposed to adjust median costs for device-dependent APCs to the greater of the median from claims data or 85 percent of the CY 2005 median used to set the payment rate in CY 2005 and not to impose a limit on the extent to which a median cost can increase.

While MDMA applauds CMS for taking protection against large decreases in individual device APC payments, allowing a 15 percent rate change from previous calendar years still significantly perpetuates unpredictability in reimbursement and leads to limited patient access to high-technology devices and procedures. As discussed previously, manufacturers and hospitals need stability in payment rates for device-related services. Dramatic fluctuations in reimbursement rates impact the device manufacturer's ability to contract effectively, and provide a stable purchasing environment. In addition, products that suffered reimbursement cuts in the past have still not had their payment rates restored to adequate levels. The value of innovation brought by medical device companies will be lost if such companies continue to be subjected to drastic payment fluctuations, and the patient will suffer the consequences. *MDMA supports a limit on reductions for all APCs by imposing a reimbursement floor of 100 percent of the 2005 rates plus inflation (3.2%) for all device-related APCs.*

IV. External Data In Setting Device-related APCs

MDMA believes it is important for CMS to use the best available data in setting rates, whether such data is generated internally by CMS or accepted from outside sources. In particular, external data can be used to identify and adjust payment for technologies that have been underfunded in the past under the OPPS, as well as for those products and procedures that received significant cuts in recent years. To date, CMS has not taken advantage of enough opportunities to improve payment adequacy based on external data.

The impact of charge compression on reimbursement rates is a good example of the need for CMS's consideration of multiple data sets, including external data. A system based on flat cost-to-charge ratio calculations often results in significant payment inequities. Manufacturers who believe their products are disadvantaged due to differential or disproportionate markups as a result of cost-to-charge ratio calculations should be allowed to present confidential data to CMS in support of their case for more adequate payment, and CMS should incorporate external independent and manufacturer data into the median cost calculations. Doing so would help CMS assess the validity of the rates derived directly from the claims data, and incorporate appropriate supplemental data into the median cost calculations setting the proposed APC weights.

We understand that CMS believes that, in many cases, the agency is able to determine reasonable rates with its own internal data, and that using external data is essentially an "exception methodology" that gives CMS more complete information to use in setting rates. However, use

of external data should not just be an “exception methodology,” particularly where data external to the agency is the more credible data source. In situations where manufacturers and hospitals can prove with external data that products are underpaid, CMS should make every effort to utilize this external data and make appropriate reimbursements to ensure patient access to new products and devices. Furthermore, accepting external data gives CMS important supplemental data sources without committing the agency to reliance on any particular data source when setting payment rates. Consequently, accepting external data can only benefit the agency. Consistent with CMS’ goal of basing payments on the most accurate data, we encourage the agency to expand its practice of considering external data.

V. Confidentiality of External Data

As noted above, external data is often the most credible source of information for setting accurate payment rates, and we believe CMS should expand its practice of considering external data. However, it is imperative that all external data used in rate setting be made private. If such data is available for public inspection, it will discourage hospitals and manufacturers from providing this data to CMS and will frustrate the agency’s efforts to set payment rates based on the most accurate information.

If industry or hospital data is accurate and more complete than internal CMS data, it should be used to set payment rates; however, it is not necessary for this data to be made public. Without adequate assurances of confidentiality, manufacturers and hospitals will be unwilling to release to CMS proprietary information that could be useful to competitors.

In addition, detailed information on hospital acquisition costs might be impossible to obtain due to contractual obligations. Many hospital purchasing contracts contain mutual non-disclosure clauses that would be breached if acquisition cost data were publicly released, potentially exposing hospitals or manufacturers to liability. This problem would be prevented if CMS pledged to hold external data confidential and to protect this information from public disclosure.

VI. New Technology APCs

CPT Application

CMS is proposing to require that an application for a code for a new technology service be submitted to the AMA’s CPT Editorial Panel before CMS accepts a New Technology APC application for review. A copy of the submitted CPT application will have to be filed with CMS as part of the application for a New Technology APC assignment under the OPPS, along with the AMA’s letter acknowledging or accepting the coding application.

The CPT process is under the purview of the AMA, not the public or the manufacturer, and therefore it is inappropriate to link application for a New Technology APC to applying for a new CPT code. First, there are only three submission deadlines per year for CPT applications, and these do not coordinate with the quarterly schedule for filing New Tech APC applications,

potentially resulting in tremendous delays. Second, tying New Tech APC assignment to submission of a CPT application assumes that the manufacturer submits and controls the path of CPT applications. While it is possible for manufacturers to file a CPT application to the AMA, traditionally the AMA has discouraged this. Further, medical specialty societies have been slow to support applications that are not vetted through them. Manufacturers may work with the specialty societies to support an application and encourage one to be filed; traditionally the appropriate medical specialty society carries the application forward through the process. In many cases, the specialty society writes the application or takes an application draft through an internal review process, where it is finalized before being officially submitted. This means that the manufacturer may not be the recipient of a letter indicating that the application is in the system. Importantly, the process for filing a CPT application, in reality lacks consistent criteria that is necessary for a federally run program.

CPT applications are driven by individual medical specialty societies which lead to a high variability in how applications are submitted, processed, and ultimately supported. It is not unusual for a specialty society to hold an application depending on the internal workload or competing CPT applications being considered internally. It is important to note that the specialty societies and AMA's primary goal in CPT is to provide a vehicle for physician payment from both public and private payers through the establishment of a relative values that reflect the work, malpractice risk, and overhead for the physician and the physician practice that delivers the service. Since the true purpose of CPT does not align with the goals of the OPPS as a Medicare specific payment system, CMS should consider developing an alternative advisory committee of physicians and medical experts to assist in the review of New Technology APC applications.

Although CMS has proposed requiring manufacturers to merely file a CPT application (and not necessarily to obtain a CPT code), applying for a CPT code could have significant negative consequences that will impact access to the new technologies for which the New Technology APC is designed to provide access. For example, Medicare Carriers and Intermediaries have been releasing draft local coverage determinations that *categorically* deny payment for current and future Category III CPT codes. Thus, submission of a coding application might lead to assignment of a Category III CPT code – resulting in automatic non-coverage of a device, and therefore, no payment. In addition, this unilateral non-payment policy could potentially prohibit reimbursements to physicians for their services related to use of the technology. Lastly, many private payers deny or cannot operationally accept Category III codes. CMS should not require manufacturers to engage in a process where the result could be a Category III code, a determination that may have negative ramifications for coverage by the Medicare program and/or by private payers in order to apply for a New Technology APC. Many manufacturers will be unwilling to file New Technology APC applications because of this risk to provider reimbursement. Moreover, and the consequences of this policy would be contrary to Congressional intent that New Technology APCs expedite beneficiary access to new technologies. In addition, it will increase the use of unspecified codes that will have a negative impact on the OPPS data set by not providing service specific information that will contribute to appropriate APC assignment in the future.

Finally, MDMA strongly believes it is inappropriate to tie decisions about how a public program is going to reimburse new technologies to a privately run process that is not subject to public input or required to operate in the public domain. CMS has said itself on numerous occasions that it does not control CPT, and that decisions regarding CPT coding decisions are not within the agency's purview. The CPT application process as established by the AMA does not provide any opportunity for public comment or review of its decision making process. The federal government has historically promoted a policy of transparency, as seen in the Administrative Procedure Act (APA) and the Federal Advisory Committee Act (FACA). MDMA thinks that tying New Tech applications to the closed CPT application process at a minimum violates the spirit of federal transparency standards and requirements. The federal government should not require participation in an application process that allows no public review or recourse when establishing reimbursement under a federally-run and federally-funded program. CMS has been able to make decisions with regard to New Technology applications in the past without requiring an application for a CPT code.

MDMA believes this proposed new requirement to require a CPT code application to be filed in order to qualify for filing a New Technology APC application is an inappropriate use of a privately run program whose sole intent is not to serve as the payment system for the federally run Medicare Hospital Outpatient Prospective Payment System in order to introduce physician representation into the decision-making process for a federal payment system. MDMA suggests that CMS consider convening an independent or alternative group of medical experts to assist in the review of applications as necessary, to assure that Medicare beneficiaries continue to have expeditious access to new and innovative technologies.

VII. Multiple Diagnostic Imaging Reduction

Currently under OPPI, hospitals receive the full APC payment for each diagnostic imaging procedure for each service on a claim, regardless of how many procedures are performed using a single modality and whether or not contiguous areas of the body are reviewed. CMS proposes that whenever two or more procedures in the same family are performed in the same session, the first procedure will be paid at the full reimbursement level and the second at a discount of 50 percent.

MDMA agrees with the CMS position that when certain procedures are performed in the same session, a number of the resource costs are not incurred twice. However, we have concerns that CMS inappropriately relied on certain data when developing this policy. CMS utilized the Medicare Physician Fee Schedule methodology and data, rather than that of the OPPI process, in developing this policy. Second, MDMA believes that the hospital's cost-to-charge ratios and related cost reporting methodology already takes into account reductions for multiple imaging procedures. Since the OPPI methodology already accounts for the cost efficiencies of multiple procedures in the same session, an additional 50 percent reduction, as described in the proposed rule, would contradict this methodology and systematically disadvantage hospitals relative to other imaging facilities. *MDMA supports the APC Advisory Panel's recommendation that CMS delay implementation of the multiple diagnostic imaging procedure reduction for one year to allow additional time to study this proposal.*

VIII. Conclusion

We look forward to working with CMS on these and other issues of concern regarding outpatient hospital reimbursement. If you have any questions or would like to discuss these ideas further, please contact me at 202-349-7174 or mleahey@medicaldevices.org.

Sincerely,

A handwritten signature in dark ink, appearing to read "Mark H. Leahey", with a stylized flourish at the end.

Mark Leahey
Executive Director

Submitter : James Hevezi, Ph.D.

Date: 09/16/2005

Organization : American Association of Physicists in Medicine

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

9/6/05 American Association of Physicists in Medicine Letter to Hon. Mark B. McClellan, M.D., Ph.D.; re Proton Beam Therapy.

CMS-1501-P-525-Attach-1.DOC



American Association of Physicists in Medicine

One Physics Ellipse
College Park, MD 20740-3846
(301) 209-3350
Fax (301) 209-0862
<http://www.aapm.org>

September 6, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 314 G
Washington, DC 20201

Re: Proton Beam Therapy

Dear Dr. McClellan:

The American Association of Physicists in Medicine (AAPM) is pleased to submit comments regarding Proton Beam Therapy to the Centers for Medicare and Medicaid Services (CMS) in response to the 2006 Hospital Outpatient Prospective Payment System (HOPPS) proposed rule; CMS-1501-P.

AAPM's mission is to advance the practice of physics in medicine and biology by encouraging innovative research and development, disseminating scientific and technical information, fostering the education and professional development of medical physicists, and promoting the highest quality medical services for patients. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the Nuclear Regulatory Commission and various State Health Departments. AAPM represents over 5,000 medical physicists.

We would like to thank CMS for the recent significant positive changes in proton beam therapy classification and payment under HOPPS. Specifically, AAPM supports the CMS proposals to:

- **Move the intermediate and complex proton beam delivery codes 77523 and 77525 from New Technology APC 1510 to clinical APC 667 *Level II Proton Beam Radiation Therapy*.**

- **Maintain the simple proton beam delivery codes 77520 and 77522 in APC 664.**
- **Maintain separate classifications for simple, intermediate and complex proton therapies (CPT 77520, 77522, 77523, 77525)**
- **Increase proposed 2006 payments under HOPPS for all proton beam codes.**

Proton beam therapy is in the early stage of clinical adoption. The required equipment is significantly more expensive to purchase and maintain than standard radiation treatment equipment. A typical proton beam therapy center requires between \$70-\$125 million and more than three years to develop. There are currently only 3 proton therapy centers in the United States, but more centers are in development stages. For those sites establishing centers, cost continues to be a major concern, which underscores the importance of maintaining adequate Medicare payment for the technology. It is critical that CMS continue to work with the providers of proton therapy to understand and analyze the data for classification and payment, as was evident in the 2006 proposed rule, to ensure the economic viability of both existing facilities and those in various stages of construction and development.

Maintaining separate APC rates for proton therapies of varied complexity is necessary to differentiate between resource demands of different treatment levels. The 2006 proposed rates under HOPPS more accurately reflect the significant capital demands associated with developing and high operating costs of running a proton therapy center. Appropriate payment rates for proton beam therapy will ensure this leading-edge cancer therapy is available to Medicare beneficiaries. AAPM requests that CMS finalize the proposed changes to proton beam therapy effective January 1, 2006. Thank you for your consideration of our comments.

Sincerely,

James Hevezi, Ph.D.
Chair
AAPM Professional Economics Committee

Submitter : Laura Thevenot
Organization : American Society for Therapeutic Radiology and Onc
Category : Health Care Provider/Association

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

9/16/05 American Society for Therapeutic Radiology and Oncology (ASTRO) Letter to Department of Health and Human Services; re Proton Beam Therapy.

CMS-1501-P-526-Attach-1.PDF



American Association of Physicists in Medicine

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September 6, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
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200 Independence Avenue, SW
Room 314 G
Washington, DC 20201

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Maintaining separate APC rates for proton therapies of varied complexity is necessary to differentiate between resource demands of different treatment levels. The 2006 proposed rates under HOPPS more accurately reflect the significant capital demands associated with developing and high operating costs of running a proton therapy center. Appropriate payment rates for proton beam therapy will ensure this leading-edge cancer therapy is available to Medicare beneficiaries. AAPM requests that CMS finalize the proposed changes to proton beam therapy effective January 1, 2006. Thank you for your consideration of our comments.

Sincerely,

James Hevezi, Ph.D.
Chair
AAPM Professional Economics Committee

CMS-1501-P-527

Submitter : Mark Reid, CMD

Date: 09/16/2005

Organization : American Association of Medical Dosimetrists

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

8/24/05 American Association of Medical Dosimetrists Letter to Hon. Mark B. McClellan, M.D., Ph.D.; re Proton Beam Therapy Payment Classification.

CMS-1501-P-527-Attach-1.PDF



American Association of Medical Dietitians

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Region III Director
 Jennifer Puskenud, CMD

Region IV Director
 Thomas Krutnowski, CMD

Region V Director
 Anjanette Milligan, CMD

Region VI Director
 Mary Jo Ropasky, CMD

August 24, 2005

The Honorable Mark B. McClellan M.D., Ph.D.
 Administrator
 Centers for Medicare and Medicaid Services
 Hubert H. Humphrey Building
 Room 314G
 200 Independence Ave. SW
 Washington, DC 20201

Re: Proton Beam Therapy Payment Classification

Dear Dr. McClellan:

In the Proposed Calendar Year 2006 Rule: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY06 Payment Rates (CMS-1501-P) we note the following as it relates to proton therapy:

1. Maintains separate classifications for simple, intermediate and complex therapies.
2. CMS proposes to change intermediate and complex to a Clinical APC (0667).
3. Proposed payment rates of simple APC 0664 (CPT 77320 and 77523) (\$964.74) and intermediate and complex APC 0667 (CPT 77523 and 77525) (\$914.93).

We strongly support the classifications and payment rates for proton therapies and urge CMS to make it final for CY 2006. Proton therapy can improve treatment outcomes, quality of life, and our standard of care for cancer patients.

Thank you for your attention to this critical issue.

Sincerely,

Mark Reid

Mark Reid, CMD
 President AAMD

Submitter : Miss. Julie Rodda
Organization : St. Joseph's Hospital
Category : Hospital

Date: 09/16/2005

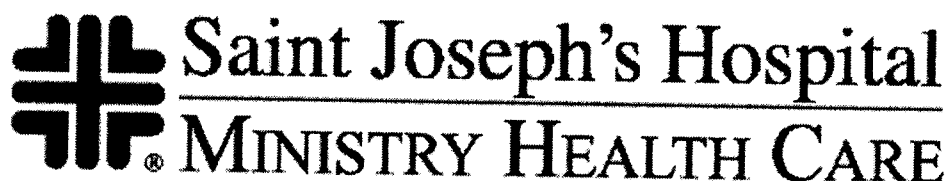
Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-528-Attach-1.DOC



611 St. Joseph's Avenue, Marshfield, WI 54449

September 16, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Submitted Electronically: <http://www.cms.hhs.gov/regulations/ecomments>

RE: File Code CMS-1501-P

To Whom It May Concern:

The following comments are submitted by St. Joseph's Hospital, a 504-bed hospital located in Marshfield, Wisconsin. These comments are in response to the 2006 OPPS Proposed Rule as published in the *Federal Register* on July 25, 2005. If you have any questions or concerns, please call any of the contacts listed at the end of this letter.

1. APC Relative Weights

Packaged services. St. Joseph's Hospital would like to thank CMS and the APC Advisory Panel for the work they have done in reviewing codes with a packaged status indicator, particularly for services that may be the sole service rendered during an encounter.

First, we concur with the proposal to move bladder catheterization codes into separately payable APCs. Likewise, we thank CMS and the Panel for assigning APCs to vaccine administration CPT codes. These are excellent steps forward and we encourage both CMS and the APC Advisory Panel's Subcommittee on Packaging to continue reviewing other packaged codes that may warrant separate payment, either through an APC payment or

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through the use of the newly proposed status indicator "Q". To that end, and in response to the APC Panel's request for additional detail, St. Joseph's Hospital offers the following recommendations to CMS on several codes that we believe warrant separate payment, particularly when they are the only service provided to a Medicare outpatient in the hospital setting.

St. Joseph's Hospital urges CMS to change the status indicators for the following codes for 2006:

- A. Non-selective Debridement CPT 97602. This code, introduced by CMS in January 2001, has a long and arduous history under OPPS. The description of the code is: "removal of devitalized tissue from wound(s), non-selective debridement, without anesthesia (e.g., wet-to-moist dressings, enzymatic, abrasion), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session."

From the outset, CMS assigned status indicator "N" for packaged services to this code. The rationale was not published until Transmittal A-02-129, in which CMS states: "CPT code 97601 is a physical therapy service and is paid under the Medicare Physician Fee Schedule. Payment for CPT code 97602 is recognized under the OPPS as a packaged service (i.e., the service is not separately paid under OPPS); however, the cost of the service is packaged into whatever other service is provided on that date. It is common for 97602 to be performed at the time of another physical therapy service in which case payment for 97602 is packaged into payment for the other physical therapy service. If a service coded under 97602 is performed at the time of a clinic or emergency visit, the E/M service must be documented in accordance with the hospital's documentation guidelines for clinic and emergency visits. If the only service provided to a beneficiary is 97602, the hospital may bill outpatient visit code 99211. Payment for 97602 will be packaged into the payment for 99211. If a hospital provides and bills for 97601 or 97602 and a clinic or emergency department visit, the clinic or emergency visit must be separately identifiable and documented in accordance with the hospital's guidelines for documenting clinic and emergency visits."

CMS views these codes as physical therapy codes. These codes are not merely physical therapy codes, but also registered nurse codes. In fact, some of the patients at St. Joseph's Hospital have registered nurses perform more wound management than therapy providers. Physicians order patients to come to the hospital for wound care management services when other services are not available. Non-selective

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debridement is the only service the patient receives.

CPT Assistant gives an excellent example in their May 2002 issue: "A 70-year-old male who developed lower extremity ulcers as a result of venous insufficiency. The assessment reveals yellow necrotic tissue adherent to the wound base. The wound margin is undurated and inflamed. There is minimal clear serous drainage noted. It is determined that the patient would benefit from autolytic debridement. The wound and surrounding skin is lightly cleansed with a nontoxic cleanser. The wound is measured at 4.8cm x 3.1cm and the depth is undeterminable. An occlusive dressing (hydrocolloid/hydrogel) is then applied. The dressing is secured with a secondary dressing. The patient is instructed to inspect the bandage daily for break-through drainage."

This type of visit takes a nurse between 30-45 minutes to assess, make the dressing change, and then instruct the patient. The only procedure performed is non-selective debridement, which is reported with CPT code 97602 along with billable supplies. Since no other service was provided, hospital-charging staff is reluctant to report another service, even though CMS has stated that CPT code 99211 can be reported in order to generate reimbursement for the packaged service. This is problematic, not only because this is not intuitive for staff charging for the services they have provided, but also because non-Medicare payers only want to see the CPT code reported for the service actually rendered. Forcing hospitals to report an E/M code to receive reimbursement is a roundabout way for paying for the non-selective debridement service. In response to our having raised this issue last year, and again in February at the APC Advisory Panel meeting, CMS stated that this code has moved to the Physician Fee Schedule (MPFS) where in 2005 it has a status indicator of "B". This further hurts hospitals because now the code cannot even be reported. Language in the 2006 NPRM (on page 42962) states: "under the MPFS, a separate payment is never made for a 'bundled' service and, because of this designation, the provider does not receive separate payment for non-selective wound care described by CPT 97602. While this code now falls under the MPFS rules, payment policy for this 'bundled' service has not changed and separate payment is not made."

CMS does not appear to realize that this neither helps hospitals nor solves the fundamental problem. In fact, CMS has now placed hospitals in the terrible position of having medically necessary visits meet the definition of an outpatient encounter and

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providing covered outpatient hospital therapeutic services with no means of payment under either MPFS or OPFS – unless, of course, hospitals once again report CPT code 99211. Furthermore, hospitals are not allowed to render services to Medicare beneficiaries and simply not charge for those services, as this would raise a compliance issue.

St. Joseph's Hospital urges CMS to carefully review the use of this code and discuss, with its own clinicians, what this service is and why it can (and does) occur as the only service provided to outpatients in the hospital setting. To facilitate CMS' review, we have provided CMS' own definitions of what constitutes a hospital outpatient, a hospital encounter, and how non-selective wound care meets the definition of coverage of outpatient therapeutic services under OPFS.

42 CFR 210.2 Defines Hospital Outpatient. *Outpatient* means a person who has not been admitted as an inpatient but who is registered on the hospital or Critical Access Hospital (CAH) records as an outpatient and receives services (rather than supplies alone) directly from the hospital or CAH. *Non-selective wound care patients are registered outpatients of the hospital.*

42 CFR 210.2 Defines Outpatient Hospital Encounter. *Encounter* means a direct personal contact between a patient and a physician, or other person who is authorized by State licensure law and, if applicable, by hospital or CAH staff bylaws, to order or furnish hospital services for diagnosis or treatment of the patient. *The nurse or therapist has direct personal contact with the patient to treat the patient. This falls under scope of practice laws for nurses and also therapists. Medical staff physicians order wound care services from the nurse or therapist on behalf of their patient that they are managing in their offices. Wound care nurses and therapists report the care back to the ordering physician.*

Publication 100-02, Chapter 6. Section 20.4.1 - Coverage of Outpatient Therapeutic Services. Therapeutic services, which hospitals provide on an outpatient basis, are those services and supplies (including the use of hospital facilities), which are incident to the services of physicians in the treatment of patients. Such services include clinic services and emergency room services. *Non-selective wound care patients meet the definition of covered outpatient therapeutic hospital services.*

Non-selective wound debridement will continue to be provided to Medicare outpatients in the hospital setting under OPFS. If CMS does not provide separate payment for this when it is the only service rendered, then hospitals that understand CMS' guidance will continue to be forced to report CPT code 99211. Others may not even charge for the service since it has a status indicator "A" under OPFS, but under the MPFS it has a status indicator "B" resulting in no separate payment.

Therefore, St. Joseph's Hospital strongly urges CMS to assign the newly proposed

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status indicator "Q" to CPT code 97602 so that separate payment can be made when this is the only payable service provided under OPPTS. The OCE can package payment for 97602 when there is another APC-payable service on the claim, and generate a separate APC payment, using the same payment assigned to APC 600.

- B. Collect Blood Venous Device 36540.** CMS continues to assign this code a status indicator "N". Physician's offices often order patients to go to a hospital for blood work in cases where the patient has a venous access device. Drawing blood for lab work from a venous device requires that a registered nurse assess the patient, and then use a sterile kit with a needle to access the device, draw the blood, and flush the port afterwards to ensure patency. It typically takes 15-20 minutes to perform this procedure. This is a much more resource-intensive service than a simple venipuncture, yet venipuncture is paid separately under the Clinical Lab Fee Schedule, while CPT code 36540 is considered packaged.

Again, hospitals will only receive reimbursement for this service when it is the sole service provided if they report an E/M visit code. As stated above, this is not intuitive for the individual charging for these services. Moreover, private payers only want the hospital to report the actual service provided -- in this case, CPT code 36540 and not the E/M code. If CPT code 36540 remains packaged under OPPTS with status indicator "N", then many hospitals will just report the E/M code instead of 36540, because it is extremely difficult to take a single service and break it into two charges (99211 and 36540) just to report that 36540 was the only service rendered. For this reason, CMS will lack accurate data on 36540.

Therefore, St. Joseph's Hospital strongly urges CMS to assign the newly proposed status indicator "Q" to CPT code 36540 so that separate payment can be made when this is the only payable service provided under OPPTS. The OCE can package payment for 36540 when there is another APC-payable service on the claim, and generate a separate APC payment, using the same payment assigned to APC 600.

- C. Withdrawal of Arterial Blood 36600.** CMS continues to assign this code a status indicator "N". Similar to the comment above about separate payment being made for a simple venipuncture, we do not understand why CMS will not make separate payment for an arterial blood draw -- which requires more effort and carries more risk to the patient than a simple venipuncture. This code is reported when blood is drawn

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from an artery for diagnostic purposes – most often as a means of drawing Arterial Blood Gases. Currently, CMS reimburses for the ABG, but not the arterial stick. It is possible to attempt to draw arterial blood and not be successful. Arterial sticks require specialized training to perform.

St. Joseph's Hospital strongly urges CMS to assign the newly proposed status indicator "Q" to CPT code 36600 so that separate payment can be made when this is the only payable service provided under OPPS. The OCE can package payment for 36600 when there is another APC-payable service on the claim, and generate a separate APC payment, using the same payment assigned to APC 600.

- D. Irrigation of implanted venous access device for drug delivery systems – (expected 2006 CPT code 96523). Irrigation of implanted venous access device for drug delivery systems – (expected 2006 CPT code 96523). In Table 27, page 42739, CMS proposes to assign this new service/code a status indicator "N". St. Joseph's Hospital cautions CMS against doing this, since occasions exist when irrigation of an implanted venous access device is the only service rendered to hospital outpatients. If this service is not separately payable, then hospitals will be faced with the problem of having to report an E/M visit code in order to receive payment. CMS should understand that private practice physicians often send patients to the hospital with an order to "flush the venous access device". Under this order, a Registered Nurse assesses the patient and the device. A sterile kit with sterile needle is used to access the device to ascertain whether the device is patent by receiving blood flow with aspiration and flushing of the device. In the instance of the removal and replacement of a device, there is additional time spent to remove the original dressing and redress the site. If allowed to go untreated, these conditions could lead to more invasive and expensive procedures, including removal of the existing device and implantation of a new device. This service would not be expected to generate separate reimbursement when it is provided on the same day as other services such as IV infusion therapy, IV push medications, blood transfusions, or blood draws. In fact, it is likely that this service will be a component NCCI edit to the above procedures and will not be able to be reported or billed when the other services are provided. Currently, hospitals must report the flush service when it is the only service provided during the visit with an E/M code in order to receive payment for the resources expended.

We appreciate the new code for this service and urge CMS to assign the newly

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proposed status indicator "Q" to CPT code 96523 so that separate payment can be made when this is the only payable service provided under OPPS. The OCE can package payment for 96523 when there is another APC-payable service on the claim, and generate a separate APC payment, using the same payment assigned to APC 600.

St. Joseph's Hospital urges CMS to assign the following packaged codes to a specific APC for payment:

- A. Fluoroscopy Greater than One Hour 76001. Hospitals should be able to report fluoro over one hour and receive separate reimbursement for this service, since it takes more time and resources than are required for fluoro under one hour (which is represented by CPT code 76000). CPT code 76001 initially started as "N" status, then was changed to "S" status and paid, then changed back to "N" again. There are a small number of cases in which fluoro is required for over an hour, and hospitals should receive separate reimbursement for this service to cover the resources they have expended. CPT 76001 is not an add-on code. A fluoroscopy procedure is either under one hour (and the provider reports 76000) or over one hour (and the provider reports 76001). Therefore, St. Joseph's Hospital urges CMS to change the status indicator of CPT code 76001 from "N" to "X" and assign it to APC 0272.
- B. Bladder Catheterization for Specimen P9612. In keeping with CMS' excellent decision to separately pay for bladder catheterizations under OPPS, St. Joseph's Hospital urges CMS to do the same for CPT code P9612. This procedure occurs in the Emergency and other Departments when the patient is unable to perform the steps necessary for a "clean catch" sample and the nurse catheterizes to obtain a clean urine sample for clinical lab testing. This service requires the same level of effort and resource use as CPT code 51701. Therefore, St. Joseph's Hospital urges CMS to treat it in the same manner as CPT code 51701 by assigning it to APC 0340 and making separate payment for this service.
- C. Placement of occlusive device G0269. HCPCS code G0269 is a procedure which has a specific device associated with it. CMS has packaged both the procedure code G0269 and the device C-code (C1760) into endovascular APCs. This makes an assumption that this device and procedure are performed 100% of the time with other endovascular procedures. The reality is that this is one option for sealing the entrance site at the conclusion of an endovascular procedure. St. Joseph's Hospital believes

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that payment would be more accurate to allow separate payment for the G0269 through an APC. St. Joseph's Hospital also believes that G0269 should be classified as a device-dependent APC, requiring the reporting of both G0269 and C1760 on the claim. C1760 would be appropriately packaged into G0269. This would enable CMS to create an edit for claims so that G0269 and C1760 both must be reported.

2. Stereotactic Radiosurgery (Cobalt-60)

St. Joseph's Hospital is concerned about CMS' proposal to combine Cobalt 60-based SRS planning and treatment delivery codes G0242 and G0243 respectively. These are two separate services and modalities and should be considered as such. Combining these two codes deviates from the general standard of practice, currently in place for charging Radiation Oncology services, in which the plan of the treatment and the actual delivery of the treatment are separately charged.

Combining the planning service with the actual treatment delivery assumes two things. First, that the plan is the same each time; in reality the plan is different based on the diagnosis, the number of lesions being treated, and the size and location of each lesion. In other words, two patients that both have one lesion may not have the same plan: one lesion could require two shots to treat due to its size, while the other could require a greater number of shots. The planning phase is often quite intricate and time-consuming, and must be done with great care, since one dose of gamma radiation could be lethal.

The second, and perhaps the more important, reason why the two codes should not be combined is because there are instances in which planning occurs but the treatment is not provided. A Radiation Oncologist stated that: "a treatment cannot be provided without the plan, but the plan can be provided/created without the treatment ever being delivered". If the two codes are combined, CMS may end up overpaying if a payment is made using the code for the day the plan is created as well as the day the treatment is delivered (only in cases when both are not provided on the same day). A more likely scenario is that CMS will end up requiring hospitals to report modifier -52 with the code when the plan is created but the treatment is not delivered. While this can be done, CMS will still pay 100% of the procedure

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payment rate and when the same code is billed again on the day of treatment, CMS will again make 100% of the APC payment unless some sort of special cross-claim logic is created in the APC to find such claims so that no overpayments are made.

Sometimes, after the patient has been framed and the MRI scan has been accomplished, problems arise that result in the actual treatment being delayed. Examples include when a lesion is outside of the framed area, or multiple lesions appear from the initial MRI scan. In these instances, additional planning is necessary to adequately treat the additional areas. Under the proposed rule, the only billable item is the planning with the delivery reported on the day of the actual treatment delivery. Without separate codes, CMS might end up reimbursing for both services (since they will occur on different days) and making double payment. CMS might require hospitals to report modifier -52 in these cases but, since reimbursement is still being made at 100%, providers would again receive full payment on both the planning day and the treatment delivery day. This becomes a problem administratively because of the adjustments that need to be made "behind the scenes" to reduce charges and to make sure the modifier is attached.

Finally, it should come as no surprise to CMS that hospitals have been confused about reporting these codes as well as the planning code for linear accelerator-based SRS (G0338) since CY 2004. For this reason, CMS should proceed carefully in its use of the 2004 claims data to set 2006 payment rates. St. Joseph's Hospital believes that, by keeping things as they are for one more year, CMS will be more likely to collect reliable data for use in setting 2008 payment rates.

St. Joseph's Hospital also understands that CMS has requested comments on the use of existing CPT codes instead of the planning and treatment delivery G-codes for Cobalt-based SRS. While this will be another change in Radiation Oncology coding/billing, St. Joseph's Hospital favors this proposal over combining planning and treatment into one code, as the codes for planning and treatment are currently separate in the CPT.

3. Device-Dependent APCs

Over the past several years CMS has employed a variety of methodologies to set rates for device-dependent APCs, and those methodologies have changed from year to year. This has been necessitated because providers have historically not appropriately reported charges and codes for procedures and devices, based on whatever reporting mandate was in place. By

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using 2004 claims data, CMS faces the obstacle of setting 2006 payments without complete and accurate information for device-dependent APCs.

Since the reporting of reinstated device HCPCS codes was optional in 2004, most providers had no sense of urgency in accurately reporting the codes. Thus, CMS does not have adequate data to use in creating the payment rates for device-dependent APCs for 2006. CMS has proposed using all single bills using claims data both with and without C-codes in setting APC rates, and has proposed to limit the downward adjustment to 85% of CY 2005 payment rates. St. Joseph's Hospital does not believe this is enough of an adjustment, however, given that the incorrectly reported claims data are similar to the situation that occurred in 2005, when no device coding existed because the codes had been deactivated.

St. Joseph's Hospital recommends that CMS freeze payment rates for device-dependent APCs in 2006 at the current 2005 payment rates. This will minimize the instability providers have experienced with the payment rates over the past several years. Furthermore, by freezing the payment rates at the 2005 level, CMS may prevent even greater payment rate fluctuation in 2007 when device C-coded claims data from 2005 are used to set payment rates. We believe the 2007 median cost data for device dependent APCs will be more similar to the current 2005 payment rates than to the ones proposed for 2006, even with the proposed 15% dampening.

At an absolute minimum, if CMS does not freeze the rate, St. Joseph's Hospital urges CMS to employ the methodology used for this year's device-dependent OPPS payment rates: to limit the adjustment of 2006 median calculations to 95% of the CY 2005 OPPS payment median, resulting in only a 5% payment decrease.

Finally, St. Joseph's Hospital does not believe CMS is using claims data with device C-codes with a nominal line item charge (i.e., \$1.00) to set payments; nor do we believe these claims should be used to create median costs and APC relative weights. In the final rule, we ask that CMS confirm that line items with a nominal charge were not used to set median costs.

Claims subject to a device recall should also not be used to develop median costs and relative weights, as these line items presumably also carry a nominal charge. CMS may need to provide clear guidance on how providers should not report devices recalled on the claim form

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using a special condition code or a value code. This would enable claims with the condition or value codes to be isolated for review and exclusion from the rate-setting process.

St. Joseph's Hospital believes that CMS erred when it stopped making separate payment for high-cost devices and instead packaged the "costs" into the related procedure APC, thus providing payment for both the device and the procedure through one APC payment. As CMS is aware, providers are not perfect in reporting items that do not generate separate payment. Unless the majority of hospitals are diligent about reporting all of their services (including packaged services) accurately and completely, payment rates will not reflect the data reported by those providers that do report correctly, since the data are averaged together. If CMS paid for high-cost devices separately, it would certainly receive accurate and complete data. Since the majority of devices are packaged, and since reporting them has been optional, the claims data remain incomplete and inconsistent.

St. Joseph's Hospital urges CMS to review the concept of paying for high-cost devices separately rather than "packaging" the costs into the procedure payment rate. A standard definition of high-cost devices would need to be created, and we recommend defining high-cost devices as those with a cost greater than 50% of the APC payment rate.

4. Non Pass-Throughs

St. Joseph's Hospital understands that CMS has proposed to pay for all separately payable drugs (except new drugs without HCPCS codes) using average sales price (ASP) plus 6%, which is similar to estimates in the physician office setting of "average acquisition cost". In addition, CMS proposes to pay an additional 2% of ASP to cover the handling cost or pharmacy overhead component of drug payments. Both components are reflected in the drug APC payment rates as published in Addendum B of the 2006 OPPS proposed rule.

St. Joseph's Hospital has concerns about the proposal to pay an additional 2% of ASP for handling costs and CMS' proposal that hospitals will be required to report new drug handling C-codes starting January 1, 2006 in order to capture drug handling charge data which CMS may use to create separate drug handling APCs in the future.

Before we detail our concerns about these two issues, St. Joseph's Hospital offers the following comments about brand vs. generic codes, payment for new drugs without HCPCS codes, and determining how to package drugs in the future.

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Brand vs. Generic

By using the ASP model, CMS no longer needs to collect brand vs. generic drug data and has, therefore, proposed to eliminate the use of the brand name drug C-codes. St. Joseph's Hospital strongly supports the recommendation to eliminate these codes, as it will simplify how providers charge for brand and generic drugs. St. Joseph's Hospital requests, however, that CMS clarify how it determines the average sales price used to reflect payment for both brand and generic drugs since the drugs available for purchase vary. St. Joseph's Hospital seeks clarification about whether CMS has taken an average price based on the volume of brand vs. generic drugs purchased by providers during a given quarter.

New Drugs Without HCPCS codes

St. Joseph's Hospital supports CMS' continued method for paying for all new drugs without HCPCS codes using C9399 and the rules published in the May 28, 2004 Transmittal 188, Change Request 3287, for reporting new drugs without HCPCS codes.

Non-Pass-Through Drugs (determining how to set a threshold for packaged drugs in the future)

St. Joseph's Hospital understands that CMS has requested comments on how to package drugs starting in 2007. St. Joseph's Hospital appreciates the opportunity to comment and strongly believes CMS should provide separate payment for all infused and injectable drugs regardless of the "per day median" cost, and only continue to package oral drugs. This approach would create consistency in payment policy between the hospital and physician settings. CMS has already begun this process by aligning payment for many separately payable drugs this year (and even more so in 2006), as well as by proposing to require the same drug administration CPT codes in both settings starting in 2006.

St. Joseph's Hospital believes that CMS cannot intend to create consistency in some areas while leaving large differentials in others. For example, physicians receive higher payments for drug administration services and are paid for multiple administrations and hours of infusion service; hospitals are not. There are, of course, reasons for this differential, based on the lack of hospital data, but this lack is expected to be eliminated as CMS collects more data from hospitals in the future. In other areas, such as drug packaging, there is no shortage of data and CMS should align payment policies and incentives so that physicians and hospitals are treated equitably beginning in 2007.

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Therefore, St. Joseph's Hospital recommends that CMS pay separately for all infused and injectable drugs, most of which, we believe, have a HCPCS code.

2006 Proposed Drug Payment Rate Methodology

St. Joseph's Hospital has no fundamental problem with CMS use of ASP+6% to set the average acquisition cost. We are concerned, however, about CMS's proposal to reimburse providers' handling costs and overhead expenses at 2% of ASP. Given that MedPAC found that pharmacy handling costs represent 26% to 28% of the total cost of providing drugs, it seems unreasonable for CMS to allocate just a fraction of that estimate to the drug payment rate to cover hospital handling costs/overhead expenses.

St. Joseph's Hospital understands that CMS reviewed three different data sets to generate the final proposal for reimbursing separately payable drugs in 2006. On page 42725, CMS states that it compared the following: 1) GAO acquisition data for 55 separately payable drugs accounting for 86% of Medicare spending for specified covered outpatient drugs; 2) ASP data from 475 drugs payable under OPPS (CMS does not include the percentage of payment these drugs constitute); and 3) mean cost data from calendar year (CY) 2004 claims (which differs from the 'median' cost calculation used in all prior years of OPPS rule-making).

From this comparison, CMS determined that ASP+8% would cover both the average acquisition cost (ASP+6%) and pharmacy handling (ASP+2%), which appears to be over-simplistic. St. Joseph's Hospital assumes that CMS did not calculate the impact of using a 'median cost' from CY 2004 claims on the 2006 proposed payment rates. CMS has arguably accounted for drug handling and overhead in the 'median' cost payments for these drugs, yet CMS proposes to pay for them using 'mean' costs. St. Joseph's Hospital requests that CMS conduct and release an impact estimate on the 2006 proposed payment rates, by drug, of the difference between using the "median cost" vs. the "mean cost" to come up with the ASP+6%+2% model.

St. Joseph's Hospital estimated our individual pharmacy handling costs and found them to be 28.95% of total pharmacy costs. In preparing our estimates we used cost report line numbers for both direct pharmacy costs (Worksheet B, Part 1, Column 0, Line 56) and indirect pharmacy costs (Worksheet B, Part 1, Column 27, Line 56 Less Worksheet B, Part 1, Column 0, Line 56). It should be feasible for CMS to conduct a similar analysis using cost report data

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from all hospitals. Despite the fact that the data would be two to three years old, CMS would nonetheless have another data source showing an estimate of average pharmacy handling costs as a percentage of total costs for all Medicare providers.

St. Joseph's Hospital is challenged to create a recommendation that is fair and appropriate for estimating pharmacy handling costs, particularly in the short time since publication of the proposed rule. Despite the results from our own data, St. Joseph's Hospital recognizes that it is unreasonable to ask CMS to increase ASP+2% to ASP+100% -- or even ASP+30% -- to cover pharmacy handling costs. We strongly urge CMS to gather additional data and study this issue further. Therefore, we recommend that CMS simply dampen drug payment rates in 2006 so they are no lower than 95% of the current 2005 drug payment rates. CMS has done this with other APC services, and we believe it is appropriate for drug payment rates.

Capturing Drug Handling/Overhead Cost Data using C-codes in 2006

St. Joseph's Hospital also wishes to comment on CMS proposal to require hospitals to report one of the three newly proposed drug handling C-codes to reflect separate line item drug handling charges. St. Joseph's Hospital wishes to describe the extremely serious financial and operational consequences that will result if CMS finalizes its proposal to require C-codes for drug handling charges for 2006.

Financial considerations

It is important for CMS to consider that Medicare providers must charge all payers in the same way. This is specified in Provider Reimbursement Manual (Publication 15, Part I, Chapter 22, §2204). It is impossible for providers to report a J-code drug to Medicare with a dollar amount that does not include handling costs, and a different (higher) charge to another payer using the same J-code. CMS seems to believe that other payers will follow its lead in separately recognizing and paying C-codes for drug handling -- but this is not necessarily true. In an environment of cost containment and cost pressures, private payers maximize their own best interest, even when this means being inconsistent with CMS. Many hospitals currently struggle with other payers to recognize some J-codes for drugs.

Even in the unlikely event that other payers follow CMS' lead, they will not all be ready on January 1, 2006, and a differential will exist from the beginning of the new process. Even if other payers accept both the HCPCS code for the drug, and a C-code for the handling charge,

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providers are likely to lose money if they are currently being paid on a percent of charges associated with the HCPCS drug code. In order to stay revenue neutral, therefore, hospitals would have to charge Medicare one (lower) charge for the J-code while charging a different (higher) charge to other payers. This is not allowable, however, as providers must bill consistently regardless of payer. Therefore, CMS should carefully consider how its new proposal to require drug handling C-codes will impact providers in general, and not just in terms of Medicare.

CMS should recognize that pharmacy handling costs are already built into the overall drug charge. For this reason, the use of special codes to capture only the handling charge will create additional work for providers. They are unlikely to report the codes accurately or set charges correctly since no separate/additional payment will be made for the use of these codes for the foreseeable future.

It appears that CMS expects providers to adjust the charge of each drug and then create new charges for each drug handling category. It is not clear if CMS expects the handling charge reported to only reflect the "handling effort/expense" of the pharmacist or total overhead for pharmacy. For example, proposed Category 2 includes "single IV solution/sterile preparation (adding a drug or drugs to a sterile IV solution)" and "compounded/reconstituted IV preparations (requiring calculations performed correctly and then compounded correctly)". A nurse can add a drug or drugs to a sterile IV solution; for example, mixing the pre-measured powder antibiotic that is packaged in a vial connected to a small bag of IV fluid (e.g., Ancef). A licensed pharmacist handles all drugs that must be compounded or reconstituted, and calculated based on the patient's body weight (e.g., Adenosine). This requires precise calculations and formulations of the drugs to ensure that the correct dosage is administered. Where there is a difference in cost between the handling performed by a nurse and that performed by a pharmacist, it is not clear if hospitals are required to report a blended or average cost. Alternatively, CMS might expect hospitals to report the actual cost based on the discipline that handles the drug.

This is just one example of how hospitals will have to develop appropriate handling charges for each C-code. Hospitals will not reduce their charges for drugs, as this would cause havoc with hospital revenue. Any change in drug pricing will take careful planning and time, far more than is available between publication of the final rule and the codes' proposed implementation date on January 1, 2006.

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Operational considerations (coding, billing and charging issues)

The proposed use of the drug handling C-codes also raises a number of operational questions that CMS must consider before moving forward with implementation. St. Joseph's Hospital questions whether CMS expects multiple line items to be reported per date of service if multiple drugs from the same drug handling family are provided. Alternatively, CMS might expect that only one drug handling C-code from each category, as applicable, would be reported on a given date of service with multiple units of service if multiple drugs from the same category are administered.

It is also not clear whether CMS will require providers to report a single revenue code with the pharmacy handling C-codes, or whether the revenue codes will need to match the actual drug revenue code reported. If the revenue code has to match the drug revenue code, then providers will have to create multiple Charge Description Master line items; this will result in increased burden to maintain the CDM. For example, if CMS allows providers to report handling charges using revenue code 636, then only three charges (one for each handling C-code) would be added to the CDM. If providers have to report handling charges using the exact same revenue code as the drug HCPCS, however, many more line items will need to be added to the CDM (i.e., handling charges will need to be set up under revenue codes 250, 636, 637, 259, etc.). The latter process is cumbersome to build and maintain.

Claims processing systems allow reporting of items under revenue codes in one of two ways: either by rolling up all items into one line item that reflects the total quantity and total charge billed under that revenue code; or by reporting a detailed listing of charges on individual line items. The revenue code assignment will dictate whether the handling codes are rolled up into one line item with everything else reported in that revenue code, or detailed out on the claim in a single line item per C-code with multiple quantities on a particular date of service. Again, claims processing systems cannot summarize some line items and detail others if all are reported with the same revenue code. Depending on the revenue code(s) assigned for these handling codes, the claim could become very long and burdensome for both the provider and payers.

Another example of an operational concern involves whether the C-code charge can be generated automatically or if it will have to be added manually on the back end of the billing cycle. Many hospitals utilize point-of-service charging in areas such as the Emergency Room, outpatient oncology units, PACU, etc. Medications in these areas are charged as they are ordered and administered. Requiring an additional charge to be entered for handling the

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medications will create a high compliance risk. First, many of these areas have secure systems (such as a Pyxis or Omnicell) for storing medications. When a medication is removed for administration, the charge is sent electronically from this system to the hospital's billing system. Adding a handling charge will require manual intervention, since these systems are not set up to assess an automated handling charge.

A sampling of other operational issues and questions related to the use of drug handling C-codes are listed below:

- If a physician's order states, "Demerol 50 mg and Phenergan 25mg to be given intramuscularly" and the nurse obtains a vial of Demerol and a vial of Phenergan and draws up the prescribed dosages into a single syringe, would CMS expect one or two handling charges to be reported? We believe that CMS expects a one-to-one relationship between the drug and the handling charge; therefore, in this scenario, two handling charges would be reported since both medications were obtained, prepared ("handled"), and injected.
- For drugs reported with a HCPCS code, is the handling charge reported per dose of the drug, per vial/amp of drug used, or per billing increment based on the HCPCS code description? Should additional units of the handling code be reported based on the number of administrations if small amounts of the drug are prepared to be given over a period of time? For example if the physicians order states: "Percocet 1 or 2 tablets for pain", and the patient requests and receives two tablets, would the provider report one handling charge? If the patient requests only one tablet but later requests the second tablet, would the provider report one or two handling charges? Each of these options results in a different quantity being reported in the units of service field for the handling C-code line item.
- Will CMS create OCE edits requiring a one-to-one match between a drug HCPCS code and a drug handling C-code?
- When a drug is prepared but not administered to a patient, due to a change in condition or physician order, will providers be allowed to report the drug handling charge since resources were expended to prepare the drug? In other words, will CMS allow a handling charge to be reported without a corresponding drug HCPCS code? If CMS plans to edit using the OCE, it will be challenging unless providers are given explicit instructions on how to report handling charges for drugs that are prepared but not administered to the patient.

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- Does CMS only expect providers to only report a handling charge for separately payable drugs?
- Will CMS make a handling payment for packaged drugs using ASP+2% or another model? How will CMS determine what this payment should be if the drugs are not reported with HCPCS?
- How does CMS define "handling" or "pharmacy overhead"? According to the MedPAC report, the dimensions of handling costs considered include: management, including regulatory compliance; storage, including inventory management; preparation, including review of drug orders and dosage calculations; transport within the hospital; and disposal of products. Within each of those categories are labor, benefits, space, equipment, supplies, and support contracts (to provide services such as waste disposal). It is not clear where other costs should be reported, such as: hospital administration, human resources, information technology, continuing education, hospital housekeeping, utilities, interest expenses, and other costs not directly related to pharmacy but which are currently spread over all hospital departments

If CMS decides to move forward with the implementation of the drug handling C-codes despite these concerns, St. Joseph's Hospital requests clarification on what status indicator CMS plans to assign to these codes.

Ultimately, the use of separate codes to capture pharmacy handling costs will only increase the operational burdens that hospitals face, and simultaneously increase their costs. St. Joseph's Hospital urges CMS to review the coding and billing requirements necessary to implement such a mechanism correctly and to truly consider the data that might be received. Before proceeding with this proposal, St. Joseph's Hospital believes CMS should study alternate mechanisms including using provider cost report data to determine the average drug handling percentage across all Medicare providers.

Therefore, St. Joseph's Hospital recommends that CMS not implement the proposed drug handling C-codes in 2006. Instead, we recommend that CMS study alternate mechanisms for obtaining handling cost data, including using the cost report to compute an average pharmacy handling percentage that may be used in the future along with the ASP+6% model. We offer our specific thoughts on how CMS might use the cost report below.

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St. Joseph's Hospital believes CMS can use existing cost report data instead of requiring providers to report the drug handling C-codes. We believe that CMS has the needed worksheet/line item detail from the cost report but, if not, CMS can work with the Fiscal Intermediaries who do have it. Moreover, there is a precedent under OPPS for CMS to instruct its FIs to provide specific cost report calculation details to its providers to obtain specific data required by CMS and FIs and to make appropriate payments. Examples include the detailed guidance CMS released regarding calculation of the payment-to-cost ratio in the early years of OPPS and, more recently, the guidance related to calculating the outpatient cost-to-charge ratio. In both cases, providers were able to respond to their FIs who, in turn, use the data for payment purposes.

We believe that CMS can use a similar method to obtain each provider's pharmacy handling percentage and urge CMS to conduct this exercise as soon as possible. We do not expect CMS to use the calculated overhead percentage from one, two, or even 20 hospitals. We do believe, however, that CMS can conduct a similar analysis using cost report data from all hospitals, or provide explicit guidance to providers through the FIs that results in the uniform collection of the pharmacy overhead percentage from all providers.

We believe that CMS will receive many comments on this issue and that estimates of pharmacy overhead will range greatly. CMS should recognize that this is, in part, due to the different interpretations of pharmacy handling costs/overhead expenses. St. Joseph's Hospital is concerned that the terminology used by CMS about "expenses above and beyond acquisition expense" may inadvertently lead to the exclusion of certain categories of legitimate overhead expenses. Conversely, it might inadvertently include direct expenses that are not handling/overhead expenses.

For example, the indirect expense of maintaining electronic medical records for medication administration records is crucial and valid as a pharmacy expense, especially given the Institute of Medicine initiatives to automate pharmacy drug dispensing to prevent errors. This is clearly a legitimate pharmacy handling or overhead expense. An example of another legitimate expense that should not be categorized as handling/overhead is a face-to-face pharmacist consultation with patients for medication therapy management. If CMS accepts St. Joseph's Hospital recommendation, and provides instructions for FIs to use with providers to collect a pharmacy handling percentage estimate, the instructions should contain a comprehensive definition of what can and cannot be included in the estimate so that CMS will receive comparable data.

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Self-Administered Drugs

Finally, St. Joseph's Hospital requests CMS to clarify two issues related to requirements for reporting self-administered drugs. The first has to do with whether or not handling C-codes must be reported for these items, and if the costs will be considered non-covered similarly to the drugs themselves being non-covered. If the drug handling C-codes are non-covered, St. Joseph's Hospital seeks clarification if CMS sees this payment as being the beneficiary's responsibility.

Our second issue, with respect to self-administered drugs, concerns beneficiary questions that may arise from the new Part D coverage beginning on January 1, 2006. The Medicare Online Manual Publication 100-04, Chapter 1 Section 60 gives hospitals two choices for billing non-covered self-administered drugs: 1) bill A9270 with modifier -GY in the non-covered column of the claim with other covered services to communicate that this is a statutory non-covered charge for which the patient is liable; or 2) separate the non-covered charges onto a separate claim with condition code 21.

The UB-92 claim form will contain the same minimal drug detail regardless of which billing method the hospital chooses. Drug line-items will show the revenue code, the date of service, units of service, and the total charge for the line-item. There will be no specific detail related to the actual drug that was administered if HCPCS code A9270 is billed. Furthermore, when the denial is obtained from Medicare and the liability reported on the beneficiary's explanation of benefits (EOB), the statement that the hospital sends the beneficiary would not (as it does not today) contain any detail on the actual drug that was administered.

For example, a beneficiary has an outpatient visit and receives aspirin for pain and atenolol for high blood pressure. Both of these drugs are non-covered, self-administered drugs. The hospital chooses to submit these charges on a separate claim form (option 2, described above). The UB-92 claim form submitted to Medicare shows the following:

Revenue Code	Revenue Code Description	Date of Service	Units	Charges
637	Pharmacy Self Administered	9/1/2005	4	\$5.00

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The beneficiary will receive a hospital statement showing the following:

Date	Service Description and Quantity	Total Amount
9/1/2005	Pharmacy Quantity 4	Amount \$5.00

With the new Part D prescription drug benefit beginning January 1, 2006, patients will expect their hospital outpatient drugs - SADs (self administered drugs) - to be covered. CMS has confirmed that *prescription drugs* will be covered, with its statement on page 4268 of the January 28, 2005 Final Rule. We would like clarification of CMS definition of prescription drugs and how this applies to the SADs.

St. Joseph's Hospital is struggling with how hospitals can help beneficiaries understand why they will continue to receive hospital statements and a bill for hospital outpatient drug charges when the beneficiary has the new prescription drug Part D benefit and believes that their hospital outpatient drugs are covered under Part D. St. Joseph's Hospital seeks guidance from CMS about how to respond to beneficiaries who want hospitals to help them apply for and receive Part D coverage for prescription drugs. St. Joseph's Hospital is deeply concerned that beneficiaries will be confused about the new coverage process, and is interested in working with CMS to address these issues now so that the implementation of Part D is successful next year.

5. Vaccines

St. Joseph's Hospital appreciates CMS proposed changes for vaccines and vaccine administration and urges CMS to make these changes final. The status indicator changes proposed for influenza and pneumococcal vaccines will greatly aid with immunizations provided in emergency room and other outpatient settings. We would like CMS to clarify, however, that the status indicator change for HCPCS codes G0008 and G0009 will not impact our current method of roster billing for these vaccines when administered in hospital outpatient departments. We do not believe this is the case, but would appreciate CMS clarifying this in the final rule.

In addition, St. Joseph's Hospital strongly supports CMS proposal to pay separately for vaccine administration services -- as shown in Table 28 -- and urges CMS to make these changes final for 2006.

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St. Joseph's Hospital would like CMS to clarify what we believe to be a typo in the middle column of page 42739. We believe CMS intends for hospitals to report administration of the hepatitis B vaccine using codes 90741 and 90742, rather than codes 96471 and 96472 as listed in the proposed rule.

6. Drug Administration

Last year, St. Joseph's Hospital supported CMS proposal to require providers to use CPT codes to report drug administration services, as this would ease the operational burden of reporting Q-codes to Medicare and CPT codes to other payers. CMS proposes to continue requiring hospitals to report CPT codes, and St. Joseph's Hospital continues to support that process, in principle. The new 2006 drug administration CPT codes are, however, fundamentally different from the current 2005 CPT codes in the number of codes available, the description of the codes, the logic behind the codes, and the narrative CPT text providing guidance on how to use the codes. As a result of these differences, hospitals face an exponentially greater challenge in implementing the new codes and rules than they did when the change was made from Q-codes to 2005 CPT codes.

CMS stated that it could not release the actual 2006 CPT codes and descriptions because they were unavailable. Instead, CMS has released the expected descriptions of these codes, based on the temporary HCPCS G-codes that physicians use in their private practice settings. St. Joseph's Hospital thanks the AMA for responding to requests to release an advance copy of the 2006 CPT drug administration codes and descriptions, which enabled providers to review the actual codes as part of the formal OPPS comment period.

St. Joseph's Hospital understands that, although many more codes will be required for reporting drug administration services, CMS still intends to pay hospitals under OPPS on a "per visit" basis, as is done today. This means that hospitals will bill all of the relevant CPT codes that correspond to the services provided, but payment will continue to be limited by the OCE's collapse of multiple billed services that group into the same APC into a single APC payment, unless modifier -59 is present to indicate that a separate encounter occurred on the same date of service. CMS must continue to make "per visit" payments for another year, as it lacks CPT code-level data upon which to base more refined drug administration payment rates. CMS should recognize, however, that the 2006 CPT book includes many more drug

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administration codes, and that the new codes and descriptions are completely different in their "logic". This means that providers will need to receive comprehensive and detailed guidance from CMS, along with clinical examples and plenty of time, if they are to adapt to the new codes and rules.

Before proceeding with our specific recommendations related to the use of the 2006 drug administration codes, St. Joseph's Hospital reminds CMS that drug administration services are generally assigned ("charged") at the departmental level or at the point of service. Thus, drug administration CPT codes are embedded in the Charge Description Master (CDM) and departmental staff (often clinical staff) is responsible for charging the appropriate codes based on the services provided to the patient under their care. Drug administration services typically are not coded by Health Information Management/Medical Records or individual coders, and this change cannot easily be made, given the shortage of coding staff and the increased delay in submitting claims to Medicare likely to result if drug administration services also have to be coded by HIM/Medical Records staff.

To that end, St. Joseph's Hospital asks CMS to consider the following very carefully:

- The new CPT codes were created at the 11th hour last summer and converted to temporary G-codes for use in the physician setting in 2005. The G codes were created to provide physicians with a way to bill for each and every instance, or combination, of drug administration service(s) provided, to off-set the significant drug payment decreases required by the Medicare Modernization Act (MMA). Physicians in their private settings receive payment for almost every single G-code today and, hence, will receive payment for every 2006 CPT code billed. Furthermore, physicians receive separate payment for each drug administered. This is not the case in the hospital setting.
- CMS must recognize that "one size does not fit all" when it comes to the use of CPT codes. We have seen this discrepancy with many different codes including the conscious sedation bulls-eye codes in Addendum I, evaluation and management codes; critical care codes, modifiers and others. CMS has been forced to provide separate guidance to hospitals on how to "interpret", "use", and even "ignore" certain CPT codes (or parts of the CPT description) because the codes are not applicable in the hospital setting. St. Joseph's Hospital asks CMS to keep this history in mind as it reviews our comments and recommendations below.

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- It will be virtually impossible for hospitals to implement separate codes for initial, subsequent, and concurrent injections and infusions, since patients “flow” through hospitals in a way that is fundamentally different from how they are treated in a physician’s private setting. In hospitals, which operate on a 24-hour basis, patients often move from one care area, or department, to another; charges are commonly entered by each department in “real-time”, without the departments necessarily knowing what services other departments have already charged. The concept of “initial” as the primary reason for the visit is impossible to automate using the CDM.
- The new codes and descriptions are not intuitive, and will be a nightmare for clinical and coding staff to accept. One example is the concept of only reporting one “initial” service code, where initial means the “primary reason for the visit”. A second example is reporting an additional hours’ code or an additional sequential injection code when the first hour or first injection have not been reported. These requirements simply do not make sense and are artifacts of codes created and defined by physicians for physicians’ office use last year. Clinical staff charging at the point of service will not comprehend charging for an additional hour’s hydration code when the first hour hydration code has not been charged. In fact, hospitals will have to “un-train” staff because CMS has previously stated that an additional hour code (i.e., 90781) should not be reported without the first hour code (i.e., 90780). The new 2006 CPT codes rely on the concept of “initial service”, which means that all other services provided must automatically be reported as “additional” “subsequent”, or “concurrent”. The fundamental problem hospital charging staff will have with this concept is that it crosses routes of drug administration and will therefore be intuitively difficult to accept.
- Two new CPT codes, 90767 and 90768, for sequential and concurrent infusion respectively, do not follow the hourly structure of the other infusion, hydration, and chemotherapy infusion codes. The proposed 2006 CPT code narrative, released early by the AMA for review, states: “these codes are reported once per sequential infusion or once per encounter for concurrent infusion”. It will be burdensome for hospital staff to apply four different sets of definitions for similar services: initial, additional, sequential, and/or concurrent.

If the descriptions and rules for these CPT codes are implemented in the hospital setting without exception, and as written in the 2006 CPT drug administration section, it will be impossible for hospitals to implement them without heavily involving medical records staff

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and coders. These staff will be required to code each drug administration claim rather than allowing these services to be charged at the point of care. Furthermore -- and possibly the most difficult issue to accept as a result of the "initial service" concept -- CMS could inadvertently stop paying for services in the future. St. Joseph's Hospital does not believe that CMS intends for this to happen, and hopes that this is simply an oversight, but it is one that must be addressed in the final rule. We offer an example below, followed by our recommendation for how to handle it:

A patient is scheduled for a one hour chemotherapy infusion visit. During the course of that visit, an emergency medical condition arises and the patient is taken to the emergency department where hydration is provided followed by an intravenous injection. The patient is then stabilized but needs to be observed. The physician orders two hours of observation and orders another two hours of hydration to continue.

In this example, drug administration services are charged in three different departments. Even if we accept that each department will know what the others provided, and are able to comply with the concept of "initial service", hospitals continue to face a payment reduction given the status indicators that CMS assigned to the descriptions of drug administration services in the 2006 proposed OPPS rule for expected new codes.

The table below shows the codes, descriptions, status indicators, APCs, and payment rates generated today -- as well as those expected in 2006 if CMS forces hospitals to abide by the concept of reporting only one "initial" service code.

2005 CPT/HCPCS and Units	SI	Description	2005 APC	2005 Payment Rate	2006 CPT/HCPCS and Units	SI	Description	2006 APC	2006 Proposed Payment Rate
96410 x 1 unit	S	Chemotherapy by infusion, up to one hour	117	168.29	96413 x 1 unit	S	Chemotherapy administration; intravenous infusion technique; up to one hour, single or initial substance/drug.	117	192.14
90780 x 1 unit	T	Infusion by other than chemotherapy, up to one hour	120	111.80	90761 x 3 units	N	Intravenous infusion, hydration; each additional hour, up to eight (8) hours.	N/A	0.00
90781 x 2 units	N	Infusion by other than chemotherapy, each additional hour up to 8	N/A	0	N/A	N		N/A	0
90784 x 1 unit	X	Intravenous IV push injection	359	49.54	90775 x 1 unit	X	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug.	359	49.33
TOTAL								TOTAL	

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As the table indicates, no payment will be generated for the hydration service started in the emergency department and continued in observation, since hospitals will not be allowed to report another initial service code (chemotherapy is the initial service). If the 2006 CPT codes are implemented without exceptions and clarification, the nomenclature will result in non-payment for services that hospitals currently are paid for today, resulting in a significant decrease in payment as shown above which we do not believe is what CMS intended.

If CMS allows hospitals to ignore the concept and word "initial" in each CPT drug administration code, the hospitals would in fact be able to report the following codes to describe the services provided in the above example

2006 CPT/HCPCS and Units	SI	Description	2006 APC	2006 Proposed Payment Rate
96413 x 1 unit	S	Chemotherapy administration; intravenous infusion technique; up to one hour, single or initial substance/drug.	117	192.14
90760 x 1	S	Intravenous infusion, hydration; initial, up to one hour.	120	119.83
90761 x 2	N	Intravenous infusion, hydration; each additional hour, up to eight (8) hours.	N/A	0
90775 x 1 unit	X	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug.	359	49.33
			TOTAL	

Ignoring the word "initial" would free hospitals to report the payable CPT code 90760, which automatically resolves the non-payment problem illustrated in the first table above and mitigates the financial impact that we again do not believe CMS intends.

If CMS does not allow providers to ignore the word "initial", it will have to find another way to make the additional hours codes payable when used in conjunction with some other "initial" services code.

We do not believe that CMS expects to deny payment in 2006 for the same medically necessary services for which it pays today. CMS can make the codes payable by creating

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special logic in the OCE, or by requiring hospitals to use modifiers, but both of these solutions are administratively burdensome and inferior to our recommendation that CMS allow providers to ignore the concept and word “initial” in every 2006 CPT drug administration code.

This example clearly illustrates that the codes and descriptions created for the physician setting, now a permanent part of the CPT book, simply cannot work in the hospital setting unless certain exceptions are made and tailored guidance provided. Again, it is not feasible to use codes that were created explicitly for use in one setting in a second setting that is fundamentally different in its structure, staffing, coding/billing/charging, and other operational functions.

St. Joseph’s Hospital reviewed each 2006 drug administration CPT code in detail and applied the codes to current clinical examples to see if the codes were easy to use, and to identify the key questions raised. We took the time to do this in order to provide CMS with recommendations that St. Joseph’s Hospital believes are the most reasonable to facilitate an easy implementation of the 2006 drug administration CPT codes starting on January 1, 2006:

- CMS should clearly instruct providers what parts of the CPT text, code descriptions, and narrative hospitals may ignore for reporting under OPPS. At a minimum this means the concept and word “initial” should be ignored for the purposes of reporting drug administration services to CMS. This also extends to the multiple references to “physician supervision” and advanced practice training for administering staff. St. Joseph’s Hospital expects CMS to follow precedent and instruct providers to disregard this language. CMS has a history of instructing providers to “ignore” certain parts of the CPT definition and/or narrative as it relates to the provision of services in the hospital setting (as described above), and this should not be a problem in 2006.
- St. Joseph’s Hospital urges CMS to benefit the provider community by working with the AMA to include an introductory, two- to three-page “caveat” section in the CPT book. This section would clearly state which CPT codes, language, guidance, and narrative information hospitals can ignore because the information is irrelevant in this setting. This would be enormously helpful in reassuring hospital staff that they are allowed to disregard (or ignore) the parts of the CPT that are inapplicable. This will likely reduce the questions that CMS receives from hospitals and others about this topic, while increasing the accuracy and completeness of claims data and aiding future rate setting.

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- CMS should carefully review the 2006 CPT codes, along with all of the previous transmittals released in relation to OPPS billing for drug administration services, to determine what will carry over for 2006 and what needs to be updated. CMS should not simply re-release the 2005 guidance to physicians for hospitals to use in 2006. The hospital guidance must contain numerous clinical examples including combinations of services, patients that cross departments, and visits that extend overnight or over more than one date of service. The clinical examples should also include documentation time, as that is now a critical piece of the puzzle in determining what codes to report.
- CMS should clearly define all concepts associated with the terms “sequential”, “concurrent”, “diagnostic”, “prophylactic”, and “therapeutic”.
- CMS should define what solutions are administered as hydration with codes 90760/90761 and confirm that these solutions should be reported under revenue code 258 for IV solutions.
- CMS should clearly define what is meant by the administration of “single or initial substance/drug” (e.g. as in 90774), and provide examples of when it would be inappropriate to report these codes. Today, hospitals report an administration for each medically necessary drug administered. For example, if two drugs are mixed together and administered via one syringe, then only one administration code is reported. If the same drug is injected more than once in a period of time due to medically necessary reasons, then multiple administrations are charged, even though the same drug is being given. St. Joseph’s Hospital requests clarification about how this will change with the new 2006 CPT codes.
- CMS must only apply the “initial” service concept on a service-location basis (e.g., each department would charge for what happens in their department based on the applicable codes), as opposed to a visit or claim level basis, even though payment will still be made on a “per visit” basis. This is critical in a hospital setting since patients can receive treatment across multiple departments. The simplest way to achieve this to allow hospitals to simply ignore the “initial” service concept as recommended above.

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- Today, CMS only expects to see modifier -59 reported with drug administration services when two or more separate and distinct visits occur on the same date of service. We request that CMS confirm that this is still the only time it expects hospitals to report modifier -59 with respect to drug administration services.
- Our final recommendation is for CMS to carefully review the Excel table that follows below. It includes 2006 CPT drug administration codes for which St. Joseph's Hospital makes specific recommendations to CMS.

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2005 CPT Code	2006 CPT Code (Preview)	2006 Description (Preview)	PRT Recommendation	Expected Result of Accepting the Recommendation
90780	90760	Intravenous infusion, hydration; initial, up to one hour.	Ignore the word "initial". Clearly define hydration.	Providers can report this for pre-or-post hydration given with chemotherapy or other services (as is allowed today)
90781	90761	Intravenous infusion, hydration; each additional hour, up to eight (8) hours.	Clarify how to report infusions > 8 hours. If similar to today with an additional line item, then reiterate this.	Minimizes confusion for providers
90780	90765	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to one hour.	Ignore "initial" and explain how this code is different from the hydration code.	Providers consider hydration as a therapeutic service. Therefore, clarifying the difference between the two will minimize confusion.
90781	90766	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour, up to eight (8) hours.	Clarify how to report infusions > 8 hours. If similar to today with an additional line item, then reiterate this.	Minimizes confusion for providers
n/a	90767	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion, up to one hour.	Define what additional sequential means in terms of the sequence of events or if the sequence does not matter then state that clearly	Minimizes confusion for providers
n/a	90768	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion.	Specify concurrent; does this relate to two or more items being infused at the exact same time per nursing documentation?	Minimizes confusion for providers
90784	90774	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug.	Ignore "initial" and indicate this code should be reported for the first injection provided. Clarify definition of single substance/drug.	Minimizes confusion for providers
90784	90775	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug.	Clarify definition of new substance/drug; if the same drug is given over time, then would multiple units of 90774 be allowed? If two drugs are mixed and provided through one injection, would two codes be submitted to signify the "new drugs"? Implementing the use of this code will be difficult so CMS should provide clear guidance and monitor its use as hospitals are likely to report multiple injections using 90774	Minimizes confusion for providers

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2005 CPT Code	2006 CPT Code (Preview)	2006 Description (Preview)	PRT Recommendation	Expected Result of Accepting the Recommendation
96400	96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic.	Publish and maintain a set of non-hormonal anti-neoplastic drug codes	Takes the guesswork away from hospitals about identifying non-hormonal cancer drugs
96400	96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic.	Publish and maintain a set of hormonal anti-neoplastic drug codes	Takes the guesswork away from hospitals about identifying hormonal cancer drugs
96408	96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug.	Ignore "initial". Clarify definition of single substance/drug.	Minimizes confusion for providers
96408	96411	Chemotherapy administration; intravenous, push technique, each additional substance/drug.	Implementing the use of this code may be difficult so CMS should provide clear guidance and monitor its use since hospitals are more likely to report multiple units of CPT code 96409.	Minimizes confusion for providers
96410	96413	Chemotherapy administration; intravenous infusion technique; up to one hour, single or initial substance/drug.	Ignore "initial". Clarify definition of single substance/drug.	Minimizes confusion for providers
96412	96415	Chemotherapy administration; intravenous infusion technique; each additional hour, 1 to 8 hours.	Clarify how to report infusions > 8 hours. If similar to today with an additional line item, then reiterate this.	Minimizes confusion for providers
96412	96417	Chemotherapy administration; intravenous infusion technique; each additional sequential infusion (different substance/drug), up to one hour.	Clarify sequential	N/A
96423	96423	Chemotherapy administration, intra-arterial; infusion technique, each additional hour up to 8 hours.	Clarify how to report infusions > 8 hours. If similar to today with an additional line item, then reiterate this.	Minimizes confusion for providers
96425	96425	Chemotherapy administration, intra-arterial; infusion technique, initiation of prolonged infusion (more than 8 hours), requiring the use of a portable or implantable pump.	Clarify how to report infusions > 8 hours. If similar to today with an additional line item, then reiterate this. CMS should also define what is meant by "portable" pump.	Minimizes confusion for providers
n/a	96523	Irrigation of implanted venous access device for drug delivery systems	Change the status indicator to "Q" as described in the packaged services section of our comments	Allows payment for this at the low level E/M visit payment when it is the only service provided without forcing providers to report an E/M code

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Without the benefit of a grace period, it is essential that CMS think about the implementation effects of this massive coding/billing change. Given that these services are now Charge Master driven, providers need time to either make a process change (e.g., begin to have HIM code these services); or update and test charging and billing systems, create charges for the new codes, update encounter forms, and train staff at the point of service about how to select the new codes to report the services provided.

CMS should not underestimate the magnitude of this change. Nor should CMS discount the enormous amount of time and resources hospitals expend to educate and train staff, update all systems and forms, and monitor the use of new codes to prevent mistakes. Therefore, St. Joseph's Hospital urges CMS to implement coding and billing guidance related to the use of the 2006 CPT drug administration codes if not in the Final Rule, then no later than November 30th, 2005. This would provide hospitals with at least 30 days to educate and train their staffs prior to the January 1, 2006 implementation date. This guidance should be comprehensive and timely. It should also include at least one clinical example for each new code and combination of codes that describe expected medical record documentation. Finally, the guidance should be free from contradictions and errors so that CMS is not required to release additional guidance and corrections many months after the codes are in place, as was necessary this year.

7. Inpatient Procedures

St. Joseph's Hospital appreciates CMS' proposal to remove 25 procedure codes from the Inpatient-only List. We continue to strongly support the APC Advisory Panel's recommendation that CMS eliminate the list altogether. Rather than using an Inpatient-only List to control provider behavior, St. Joseph's Hospital suggests that CMS rely on its Peer Review Organizations (PROs) or Quality Integrity Organizations (QIOs) to examine any questionable cases. These organizations are best equipped to handle issues related to care provided in inappropriate sites of service. We have provided some of the reasons that St. Joseph's Hospital believes the list should be eliminated below:

The decision to admit a patient is a medical decision based on a physician's assessment and requiring a specific order to admit to an inpatient status. In the past, CMS has focused on "medically necessary" services, and hospitals have worked diligently to educate physicians regarding inpatient admission criteria as well as providing and documenting medically necessary services. The Inpatient-only List inhibits providers from making medically necessary decisions about which patients require hospital admission. Hospitals are, in this manner, put in the difficult position of either asking physicians to admit patients who may

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appropriately be cared for in the outpatient setting, or providing expensive "Inpatient-only" procedures to patients in the outpatient setting and without being reimbursed.

In addition, the Inpatient-only List is very difficult to implement, since physicians resent being told what can and cannot be provided for patients when they believe the services are medically necessary and can be provided safely in an outpatient setting. This issue is beyond preventive measures that a hospital can reasonably take as it is ultimately the physician's order and intent that dictates the admit status.

Sometimes patients are scheduled for procedures that are not on the Inpatient-only List and can be performed safely and effectively in the outpatient setting; therefore, the physician makes no plans to admit the patient. During some procedures, however, a surgeon might perform a second procedure that *is* on the Inpatient-only List, or which modifies the original procedure so that it becomes one on the Inpatient-only List. The surgeon either is unaware that the second procedure is on the Inpatient-only List, or has to provide the service because to do otherwise would be poor medical practice.

In the above circumstance, in order to be paid, the hospital must find a way to immediately identify the second procedure as being on the Inpatient-only List, so that the physician may be approached about admitting the patient to inpatient care. In many cases this is unrealistic. When it is feasible, but the physician does not agree, the hospital has no recourse except to lose the reimbursement if it is to act in the best interest of the patient. In most hospitals, identification that the second procedure is on the Inpatient-only List does not occur until the record reaches the coding department following discharge. Once a patient is discharged, the admit status cannot be changed to an inpatient admission status. The hospital is forced to bill the claim as an outpatient knowing there will be no reimbursement.

In the event that CMS chooses not to eliminate the Inpatient-Only List, St. Joseph's Hospital requests that CMS post the Inpatient-only List on the physicians' web-page of the CMS website and provide background detail on the Inpatient-only List. We also request that CMS discuss this issue on the Physician Open Door Forum, in the MPFS proposed and final rules. We also request that CMS require carriers to post the Inpatient-Only list in their educational materials. In this fashion, CMS will educate physicians and facilitate hospitals' education efforts with physicians.

St. Joseph's Hospital also requests CMS to review Category III CPT Codes as soon as they are released to determine if they belong on the Inpatient-only List. We urge CMS to provide

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its rationale for new codes and services added to the Inpatient-only List in a proposed rule so that providers can submit comments. **St. Joseph's Hospital also asks that CMS clarify in the final rule that just because services are NOT on the Inpatient-only List does not mean that they can only be provided in the outpatient setting. In other words, CMS should make clear that it has NOT created an "outpatient-only list".** This will help providers to communicate clearly with other payers who often use a code's absence from the CMS' Inpatient-only List to identify services that can only be provided in the outpatient setting and will deny if done as an inpatient even if it is medically necessary. We know this is not the intent, which is why we kindly request CMS to state that fact in the final 2006 OPSS rule.

Finally, St. Joseph's Hospital continues to urge CMS to consider removing the following codes from the Inpatient-only List as they can -- and often are -- provided safely in the outpatient setting:

- *CPT code 58260 (vaginal hysterectomy not including tubes and or ovary)*
- *CPT code 63075 (Discectomy)*
- *CPT 44603 (Suture, small intestine), 44602 (Suture, small intestine) and 44604 (Suture, large intestine)*
- *CPT 49000 (Exploration of abdomen)*
- *CPT 58940 (Oophorectomy, partial or total, unilateral or bilateral)*

St. Joseph's Hospital again asks CMS to go beyond using the 60% threshold in determining what procedures are acceptable to be provided in the outpatient setting. So long as payment is tied to the procedure being performed in the inpatient setting, providers will be discouraged from finding new and safe ways to perform the procedures on an outpatient basis — despite advances in new technologies. In addition, it may be appropriate for the same procedure code to sometimes be performed as an inpatient procedure, and sometimes as an outpatient procedure, based on medical necessity. This should be based on the physician's judgment and individual patient situation rather than on the Inpatient-only List.

Please note that some Fiscal Intermediaries are now instructing hospitals to move the Inpatient-Only CPT to the non-covered column of the UB92 claim and re-submit the claim to allow payment for the other services under OPSS. St. Joseph's Hospital is concerned that, under this system, some hospitals receive payment when other hospitals do not. St. Joseph's

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Hospital asks CMS to issue instructions to ensure that every FI handles such situations in the same way, as it is not being implemented consistently by all FIs.

Finally, St. Joseph's Hospital requests that CMS review both hospital and physician utilization rates for these procedures, since physicians do not have the same restrictions on where procedures must be provided as hospitals do. This is just one of several examples of policy and/or payment differentials between hospitals and physicians noted by St. Joseph's Hospital in our comments.

8. Status Indicator

St. Joseph's Hospital supports the creation of status indicator "Q" to indicate packaged services that are subject to separate payment under OPPS payment criteria. It is not clear, however, whether this status indicator is going to be assigned to any CPT/HCPCS codes starting January 1, 2006. St. Joseph's Hospital believes that this status indicator should be assigned to several codes representing services, which can be, or are, the only services provided to patients on a given date of service. We described several of these services in detail in the section on packaged services and encourage CMS to refer to that section for our rationale for assigning the following codes status indicator "Q" in 2006:

- Non-selective Debridement CPT code 97602
- Collect Blood Venous Device 36540
- Withdrawal of Arterial Blood 36600
- Irrigation of implanted venous access device for drug delivery systems (expected 2006 CPT code 96523)

If we understand the purpose of Status Indicator "Q" correctly, and the above codes were to be assigned a status indicator "Q" for 2006, then separate payment would be made for each of the codes above when the services provided are the only OPPS payable service on a date of service. Payment would be made through APC 0600. If other OPPS payable services were provided, then the OCE would not make separate payment for the above codes and would, instead, treat the service as if it were still a status indicator "N" service. If our understanding is incorrect, St. Joseph's Hospital would appreciate CMS clarifying the payment implications associated with services assigned Status Indicator "Q".

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9. Multiple Diagnostic Imaging Procedures

St. Joseph's Hospital understands that CMS has proposed to apply a 50% discount when two or more diagnostic imaging procedures from the same family of codes are provided during one session because CMS assumes the provider gains economies to scale. St. Joseph's Hospital agrees with CMS that some economies to scale are generated when similar radiology

procedures are performed during the same session, but we disagree with CMS' proposal to reduce the payment rate of the second and subsequent APCs by 50%.

Such a reduction ignores the fact that some of the economies to scale are already reflected in the cost-to-charge ratio used by CMS to arrive at the median cost data. Furthermore, St. Joseph's Hospital notes that CMS does not currently pay hospitals for procedures that take longer as a result of problems with the patient's clinical condition. If CMS implements a reduction in payments, a modifier (such as modifier -22) should also be established to indicate increased costs, when incurred. St. Joseph's Hospital recommends the additional payment be made at the same percentage as the reduction in payment being considered. CMS should instruct hospitals to apply the increased cost modifier to any affected radiology procedure; and provide specific guidelines as to what events constitute increased cost, as well as documentation needed to support the modifier.

In addition, CMS states in the proposed rule that private payers are already discounting in the same manner as proposed by CMS. We caution CMS against drawing assumptions about what private payers are doing and the extent to which they follow Medicare's lead.

St. Joseph's Hospital also has questions about the family of codes CMS proposes. For example, St. Joseph's Hospital disagrees with CMS' proposal to discount CPT code 76830 (transvaginal ultrasound, non-ob) when provided during the same "session" as CPT code 76700 (echo exam of abdomen). Routinely, when a patient has a transvaginal ultrasound following ultrasound of the abdomen, the patient must leave the room to empty her bladder, the room must be set up again for this separate procedure, and a different probe installed. In this situation, we do not believe economies of scale exist that would warrant a 50% payment reduction for the second procedure. Therefore, if CMS chooses to move forward with its proposal, St. Joseph's Hospital urges removal of the transvaginal procedure represented by CPT code 76830 from the list of services included in Family 1.

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CT Abdomen and CT Angio Abdomen provide a second example. To the best of our knowledge, these services are never provided during the same session, yet CMS has assigned them to the same family of codes. Again, if CMS proceeds with its proposal we recommend that it only assign procedures to the same family if the procedures are commonly performed during the same session, and exclude those that are rarely performed in the same session.

St. Joseph's Hospital is also not clear on what CMS means by separate "session". If CMS proceeds with this proposal, the term "session" must be explicitly defined so that providers know when they can and should use modifier -59 to signify that multiple diagnostic radiology procedures were performed on the same date of service, but NOT during the same session. CMS will need to define "session" in a way that distinguishes it from other terms, such as "encounter" or "visit", so that hospitals will use modifier -59 appropriately in order to be paid 100% for both or all of the subsequent procedures provided (if done during different sessions).

St. Joseph's Hospital urges CMS to delay implementation of this proposal until it has fully studied and analyzed both provider claims and cost report data to determine if, in fact, a further reduction in payment is warranted or if economies to scale are already being captured through the departmental cost-to-charge ratio. In addition, St. Joseph's Hospital encourages CMS to consider working with the AMA to simply create new CPT codes that describe commonly combined procedures so that data can be more systematically collected and payment rates naturally be set from provider charges for these combined procedures as reported through the claims data. Furthermore, this would ensure that the ordering physician intended for both exams to be performed and a single radiologist report would be produced that addresses the combined exams.

10. Interrupted Procedures

Since implementation of the OPPI in 2000, CMS has required hospitals to report modifiers – 52, -73, and -74 to indicate procedures that were terminated before their completion. Over the years providers have struggled to understand how to use these modifiers, in particular whether conscious sedation is considered anesthesia by CMS or not. Clarification on this issue was released earlier this year, and while helpful CMS needs to continue addressing other questions providers have about the use of these modifiers.

For CY 2006, CMS is proposing to decrease payment for services when modifiers -52 and -74 are reported. St. Joseph's Hospital disagrees with this proposal and explains why below.

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Modifier -52

St. Joseph's Hospital requests that CMS continue making full payment (100% of the APC payment) for services reported with modifier -52. St. Joseph's Hospital believes that the same level of resources is consumed whether the service is provided in full or discontinued part way through the procedure. Clearly, procedures that are cancelled or discontinued at the very start due to patient's being nervous or worried should not be charged. The procedures under discussion are already underway, which is why St. Joseph's Hospital believes that the same amount of resources (and, in many cases, even more resources) are consumed than would be required to complete the normal procedure. This is true both for modifier -52, and even more so for modifiers -73 and -74, which are discussed below.

An example is CPT 74485 (dilation of nephrostomy, ureters or urethra), in which a patient presents for dilation of both ureters due to bilateral strictures, and multiple dilating balloons are used. In a hypothetical case, the dilating balloon is passed into the stricture in the right ureter, the balloon is inflated, and the stricture is opened. The balloon is then moved to the left ureter. The balloon, however, will not cross the stricture, and a smaller balloon must be selected. In this case, several balloons of different sizes are used in an attempt to dilate the stricture. The patient is likely to complain of discomfort, which may result in the physician terminating the procedure. Because this CPT code includes "ureters", the scenario described would be correctly reported with modifier -52. The resources and supplies required for the failed procedure are actually higher than for an uncomplicated, completed procedure. If the attempt to dilate the left ureter had been successful, fewer supplies and resources would have been used, and the procedure reimbursed at 100 percent. However, because the left stricture required multiple attempts to dilate (the stricture), the hospital incurred the cost for more balloons and consumed more procedure time.

St. Joseph's Hospital does not believe that circumstances such as "equipment failure" are an acceptable reason to apply modifier -52. Several attempts and time may be exhausted to complete a procedure that is not successful -- such as an attempt to re-position a patient to complete a procedure, or several attempts to establish a PICC line insertion. In both scenarios, resources and supplies are utilized. All of the same resources have been exhausted even though the procedure is ultimately reduced. In some cases, more resources are utilized due to the patient's size or difficult anatomy, or because several attempts are made that increase time and overhead. St. Joseph's Hospital believes it is inappropriate for CMS to reduce payment for procedures reported with modifier -52 from 100% to 50% and urges CMS to better

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understand provider operations and resource consumption before implementing such a decision. Given the relatively low frequency with which this modifier appears in the claims data, St. Joseph's Hospital believes providers are either still very confused about when to report these modifiers (and are simply not reporting the services at all), or they are just not canceling or discontinuing as many procedures as some might think. Without further review, providers who truly must discontinue procedures and who incur the expenses will face unwarranted financial impact.

Modifier -73

St. Joseph's Hospital concurs with the APC Advisory Panel and recommends that CMS make full APC payment for services reported with modifier -73 because of significant use of hospital resources in preparing the patient for the treatment or operating room. St. Joseph's Hospital further requests that CMS remove the language "taken into the treatment room," from the current policy because, in many cases, it prevents the legitimate application of modifier -73.

Patients are often prepared for surgery in various settings of hospital based on space availability, including pre-operative and holding areas. Preparation in these areas incurs the same costs as if the preparation occurred in the treatment or operating room. The current definition of modifier -73 requires the surgery to be cancelled in the room where the surgery is to occur. Although the patient may not go to the treatment room, sterile surgical supplies have been opened and other resources (such as staff time and scheduling) consumed; providers cannot recoup these costs because modifier -73 is not allowed.

For example, a patient is registered, a medical record is created, and an initial assessment completed. The patient changes into a hospital gown and is taken to a bed or other space in a pre-treatment room or holding area. The nursing staff takes the patient's vitals and provides education in preparation for the procedure. An IV may be initiated at this time to start medications; many physicians order pre-operative medications to be given while the patient is in the holding room. Some of these medications have a sedative property, but are not considered to be anesthesia. At this point, the procedure room has been prepared for the patient, and sterile supplies opened, in order to expedite beginning the procedure as soon as the patient is taken into the procedure room and positioned on the table. Hospitals manage their resources by ensuring that procedure rooms are ready and supplies available for procedures before the patient enters the room. (Research indicates that patients become

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anxious and worried if there is a delay in beginning the procedure when they enter the procedure room. In addition, waiting to set-up and open supplies until after the patient enters the room causes cumulative delays in the surgical suite.) In this hypothetical case, the patient experiences elevated blood pressure during the final pre-procedure processing while the patient is still in the holding area, and the physician decides that the procedure must be discontinued. Clinical care must still be provided to the patient after the point of discontinuation until he or she is stable and ready for discharge

In this case, the hospital has expended a large number of resources in caring for this patient pre-operatively, but the current reimbursement to the facility is "\$0.00". The hospital cannot bill the procedure with modifier -73 since the patient did not enter the procedure/operating room. The reality is that in many cases of cancelled procedures even more hospital resources are expended than are involved in a normal procedure. Some providers bill nothing in the above example since the patient was not taken into the procedure room, while others are reporting an E/M visit code to recoup some of their costs.

Therefore, St. Joseph's Hospital requests that CMS allow providers to use modifier -73 for cancellation of procedures for patients in a holding room or a pre-operative suite when the patient is clinically prepared for surgery and resources have been utilized. When a procedure is cancelled prior to clinical preparation of the patient, there is little resource utilization and modifier -73 would be inappropriate and providers are aware of this, but CMS could reiterate this point in the final guidance. If CMS does not change the description of modifier -73 to allow hospitals to report it with procedures cancelled prior to the patient entering the treatment room, then it should clearly tell providers that they are allowed to report an appropriate E/M visit code to recoup some of the costs incurred.

Modifier -74

St. Joseph's Hospital concurs with the APC Advisory Panel's recommendation that 100% of the APC payment be made for services reported with modifier -74. This is CMS' current policy and St. Joseph's Hospital believes it should not change in any way, as providers typically face full and often increased costs when modifier -74 is used. CMS suggests that the same costs are not incurred when a procedure is canceled and suggests that providers are able to report additional services provided and receive payment for them. St. Joseph's Hospital strongly disagrees with these statements and believes CMS should rethink its position. In many circumstances, a procedure is cancelled due to the patient's anatomy or a complication of the patient's condition. This may extend the procedure time beyond the normal period. A

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hospital is not allowed to receive additional payment for the prolonged procedure time. Physicians (professional services) recoup unusual procedure services with modifier -22, but hospitals do not have the luxury of doing so.

St. Joseph's Hospital does not believe that resources are necessarily reduced when a procedure is cancelled. For example, an endoscope procedure may only be partially completed because the surgeon encounters a mass before the scope can be advanced to the furthest point (as described by the CPT code). Several attempts and time may be exhausted to maneuver around the mass and evaluate the extent of the disease. In many cases, additional costs are consumed in an attempt to complete the procedure. Full payment should be allowed for the completion of the procedure, since the full use of resources was exhausted.

Hospitals do their best to manage their resources by screening patients for possible complications that may cause the procedure's cancellation. Because each patient is unique, however, it would be impossible to anticipate and avoid all complications. Complications include -- but are not limited to -- excessive bleeding, hypotension, hypertension, tachycardia, bradycardia, and reactions to anesthesia drugs or gases. The physician and/or anesthesiologist attempt to manage complication(s) and complete the procedure, but there are times when it is in the patient's best interest to discontinue the procedure. The decision point for discontinuation will vary based on the individual situation. If a patient has a reaction to an anesthesia drug or gas, the procedure may be discontinued before an incision is made, however, significant resources have already been expended.

Once anesthesia is initiated, the hospital has every expectation that a procedure will be completed and, therefore, supplies are opened and ready for use during the procedure. (In fact, surgery departments report that expensive implants are not usually opened until the physician is sure which implant will be used; at that point, the patient is already in the surgery/treatment room.) Once the usual supplies are opened and the patient has entered the room, the supplies cannot be used for a different case. To wait to open each item until the physician is ready to use it would increase procedure time, require additional staff in the procedure room to anticipate the physician's needs, and could cause the patient to be anesthetized longer than necessary. Once anesthesia is administered, there is no turning back in terms of hospital resources being expended. The post-procedure care of the patient does not change: anesthesia must be reversed, the patient must be recovered, and post-operative pain control managed. In fact, complications that cause a procedure to be interrupted often require longer recovery

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times than would be necessary for a completed procedure, which results in increased cost to the hospital, which is not covered.

Supplies and recovery time are all packaged services and the costs are covered by the APC for the procedure; therefore, reducing the reimbursement when modifier -74 is appended will negatively impact hospitals. Many hospitals bill for surgical procedures based on the time the patient is actually in the surgical suite or procedure room. These facilities are already reporting any decrease in procedure time which will reflect the decreased cost through the claims and cost data used by CMS to set future APC payment rates.

St. Joseph's Hospital also disagrees with CMS's assertion that additional services are separately payable under OPPS and therefore the hospital's costs need not be paid through the APC payment for the planned procedure. Initiation of other APCs that are currently separately payable will not recoup costs for the cancelled procedure. Most of the services required to stabilize a patient are the same charges inherent to the procedure, such as anesthesia, recovery, staff, related supplies, and drugs (which are generally packaged).

APC payments made for additional services are intended to cover the costs for providing those services, and cannot be counted on to cross-subsidize the loss taken on the payment rate for the cancelled procedure. Services provided that generate separate APC payment would simply cover the cost of providing those APCs. Moreover, certain services that are provided as part of a surgical procedure (such as injections and infusions) are inherent to the procedure and not separately reportable. This means that, if the procedure were cancelled, providers would have to begin thinking about charging for those services, which is counter-intuitive to their training NOT to report these services because they are a part of the procedure. In short, St. Joseph's Hospital disagrees with the contention that separate APCs billed would cover the costs associated with the cancelled procedure.

Finally, CMS should recognize that the majority of the upfront costs in providing a service occur in the procedure's first hour. When the physician reaches a point at which a procedure cannot be completed, the resources have already been expended. Again, CMS' own data shows that the use of modifier -74 is infrequent. Therefore, St. Joseph's Hospital urges CMS to continue making 100% APC payment for services that are discontinued in order to provide hospitals adequate reimbursement to cover the costs they have incurred.

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Conclusion

St. Joseph's Hospital would sincerely like to thank CMS and its staff for reviewing and considering our comments. St. Joseph's Hospital is very encouraged by the policy-making process and we appreciate how our input can have an impact on future year's rules and policies. We hope the operational issues we have outlined will be helpful to CMS in considering future system changes. If you have any questions or require additional information, please contact our spokespersons listed below.

Sincerely yours,

St. Joseph's Hospital

And Representatives of St. Joseph's Hospital submitting these comments:

Julie Rodda

Julie Rodda, RHIT
Coding Specialist
715-387-7765

Nancy Gilge

Nancy Gilge
Compliance/Audit Specialist
715-387-7484

Date: 09/16/2005

Submitter : Mr. Samuel Amory
Organization : B. Braun Medical Inc.
Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-529-Attach-1.PDF

CMS-1501-P-529-Attach-2.PDF



Samuel Amory
Vice President
Renal Therapies Division

B. Braun Medical Inc
PO Box 4027
824 Twelfth Avenue
Bethlehem, PA 18018-0027

Telephone : 610-997-4477
Telefax : 610-691-1547
E-mail : sam.amory@bbraun.com

September 15, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Subject: PROPOSED 2006 MEDICARE PAYMENT RATE FOR APC 0112

Dear Centers for Medicare and Medicaid Services:

On behalf of our hospital-based customers who provide LDL apheresis therapy (CPT 36516¹) to Medicare beneficiaries with treatment-refractory familial hypercholesterolemia, I ask that you address and remedy payment rate-setting faults that have led CMS to propose a 25.6% reduction in its 2006 payment rate for APC 0112, to which this procedure is assigned.

CMS proposes to reduce the current U.S. average payment rate of \$2,127.26 to \$1,583.07, based on a much lesser relative weight of 26.6734. Whereas the 2005 payment rate roughly approximated actual hospital costs for this complex, resource-intensive procedure, we have learned from customers that a payment rate of less than \$1,600 falls substantially short of those costs.

Upon examination of 2004 median costs calculated by CMS from Medicare "single frequency" claims submissions, it is apparent that (1) claims data for our procedure and CPT 36515 are seriously corrupted and/or (2) data manipulations to arrive at those median cost values for CPT 36515 and CPT 36516 are flawed:

<i>CPT code (procedure)</i>	<i>2004 claims</i>	<i>CMS "Median Cost"</i>
CPT 36515 (protein A immunoadsorption)	85	\$1,508.16
CPT 36516 (LDL apheresis)	554	\$1,321.61
CPT 36522 (extracorporeal photopheresis)	3,545	\$2,095.68

These three procedures are appropriately assigned to APC 0112 because they have similar costs associated with disposable kit components (used in conjunction with customized apheresis and other blood and plasma-related processing), specially trained nurse operator, equipment and physical space requirements.

¹Therapeutic apheresis, with adsorption or filtration and plasma reinfusion

B|BRAUN

An examination of Medicare's current CPEP resource databases for CPT 36515 and 36516 reveals that the \$1,485 cost just for supplies used to perform a procedure coded under CPT 36516 – *before* considering labor costs, equipment-related costs, room charge or operating overhead – exceeds the entire procedural "median cost" figure of \$1,321.61 ascribed to CPT 36516 on the basis of 554 claims captured in CY2004. It is our understanding that these claims were included in the pool of roughly 4,200 claims aggregated by CMS to develop its "true median cost" of \$1,616.08 for APC 0112.

	<i>CPT 36515</i>	<i>CPT 36516</i>	<i>CPT 36522</i>
<i>CPEP supply costs</i>	\$1,410	\$1,485	\$933

Similarly, the \$1,410 cost just for supplies to perform CPT 36515 nearly equals the entire "median cost" value of \$1,508.16 arrived at by CMS.

While CPEP supply and other resource cost databases are not necessarily a precise reflection of mean or median hospital costs for these resources across the U.S., they should reasonably reflect real-world costs. Moreover, we can see that (1) supply costs are far and away the largest cost element for all three specialized apheresis procedures and (2) costs of all disposable supplies for CPT 36515 and CPT 36516 procedures exceed costs of supplies for CPT 36522 by roughly \$500 to \$550.

Given the fact that CPEP labor costs are similar between these procedures (all require several hours), and equipment amortization and maintenance costs are comparatively modest, one cannot reconcile \$500 to \$550 higher supply costs for LDL apheresis and protein A immunoadsorption procedures with "median costs" that are roughly \$600 to \$800 *lower* than the median cost for CPT 36522:

	<i>CPT 36515</i>	<i>CPT 36516</i>	<i>CPT 36522</i>
<i>CPEP supply costs</i>	\$1,410	\$1,485	\$933
<i>CMS 2004 "Median Costs"</i>	\$1,508.16	\$1,321.61	\$2,095.68

I urge CMS to closely examine the 2004 claims coded with CPT 36515 and CPT 36516, with the objective of correcting the causal factor(s) for erroneously understated costs in a very substantial share of those claims.

If individual examination of claims is not practical, and CMS cannot pinpoint a methodological error that precipitated these grossly understated costs for CPT 36515 and 36516, I urge CMS to retain the 2005 APC 0112 payment rate for 2006 to help assure that hospitals that provide LDL apheresis are not compelled by economic imperatives to stop offering this life-critical treatment for the small but very vulnerable FH population faced with no other remaining treatment options.



Thank you for your consideration of our comments and request. I look forward to a thoughtful and appropriate action by CMS that is consistent with its mandate both to fairly compensate hospital providers and protect patient access to medically necessary care.

Very truly yours,

B. BRAUN MEDICAL INC.
HELP Division

A handwritten signature in black ink, appearing to read 'Sam Amory', written in a cursive style.

Samuel Amory
Vice President

Submitter : Lynn May, CAE, CEO
Organization : American Society of Radiologic Technologists
Category : Association

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

8/7/05 American Society of Radiologic Technologists Letter to Hon. Mark B. McClellan, M.D., Ph.D.; re Proton Beam Therapy Payment Classification.

CMS-1501-P-530-Attach-1.PDF



August 7, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 314 G
Washington, DC 20201

Re: Proton Beam Therapy Payment Classification

Dear Dr. McClellan:

In the Proposed Calendar Year (CY) 2006 Rule: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY'06 Payment Rates (CMS-1301-P), CMS proposed rule we note the following as it relates to proton therapy:

1. The proposed rule maintains separate classifications for simple, intermediate and complex proton therapies (CPT-4 codes 77520, 77522, 77523 and 77525, respectively).
2. CMS also proposes to move intermediate and complex proton therapies (CPT 77523 and 77525) from a New Technology APC (1311) into a clinical APC (0667).
3. Payment rates are proposed to be \$764.74 under APC 0664 for simple proton therapies (77520 and 77522) and \$914.92 under APC 0667 for intermediate and complex therapies (77523 and 77525).

Maintaining separate APC rates for proton therapies of varied complexity is necessary to differentiate between resource demands of different treatment levels.

The proposed rates more accurately reflect the significant capital demands associated with developing and high operating costs of running a proton therapy center.

Also, it should be noted that this technology is in the early stages of diffusion and as such the number of claims data should be monitored carefully, as it is expected to be modest for the next 2-3 years, with an outlook to supporting patient access to proton beam therapy.

We strongly support the classification and payment rates for simple, intermediate and complex proton therapies as proposed in the CMS CY 2006 OPPS rule. We urge CMS to make the proposed rule its final rule for CY 2006.

This will ensure that the Nation's premier cancer treatment centers have the ability to provide cancer patients with this successful treatment.

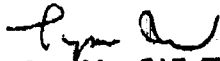
Currently, over 46,000 cancer patients have been treated with protons in many institutions around the world, including three institutions currently providing proton beam therapy in the United States. Positive clinical results from these facilities have stimulated worldwide interest in the clinical applications of proton therapy and consequently numerous facilities are in the planning or construction phases.

Proton beam therapy is in an early stage of clinical adoption. The required equipment is significantly more expensive to purchase and maintain than standard radiation treatment equipment. A typical proton beam therapy center requires between \$70-\$125 million and more than three years to develop. As a result, the number of sites establishing proton beam therapy centers has not kept pace with the clinical demand for the service. For those sites establishing centers, cost continues to be a major concern, which underscores the importance of maintaining adequate Medicare payment for the technology. It is critical that CMS OPPS continues to work with the providers of proton therapy to understand and analyze the data for classification and payment, as was clearly seen by the CY 2006 proposed rule, to ensure the economic viability of both existing facilities and those in various stages of construction and development.

Proton therapy is responsible for improving health outcomes, quality of life and our standard for cancer treatment. Appropriate payment rates for proton beam therapy will ensure this leading-edge cancer therapy is available to those we serve.

Thank you for your prompt attention to this critical issue.

Sincerely,



Lynn May, QAE, CEO
American Society of Radiologic Technologists
15000 Central Avenue, SE
Albuquerque, NM 87123
505 298-4500, x 1222
lmay@asrt.org

CMS-1501-P-531

Submitter : Leonard J. Arzt

Date: 09/16/2005

Organization : The National Association for Proton Therapy

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

8/18/05 The National Association for Proton Therapy Letter to Hon. Mark B. McClellan, M.D.; re Proton Beam Therapy.

CMS-1501-P-531-Attach-1.PDF

The
National
Association
for Proton
Therapy

August 18, 2005

Honorable Mark B. McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Room 314G
Washington, D.C. 20201

Re: CMS-1501-P –Proton Beam Therapy

Dear Dr. McClellan:

The National Association for Proton Therapy (NAPT), founded in 1990, completely supports the classification and payment rates for simple, intermediate, and complex proton therapies as proposed in the CMS CY 2006 OPPS rule and strongly recommends that CMS make the proposed rule **final for CY 2006**.

This action will ensure that the nation's proton centers will continue to have the capability to provide cancer patients with this proven non-invasive radiation treatment. It will also ensure the sustainability and future growth of proton treatment at premier regional cancer centers currently in development and scheduled to open in 2006.

As you know, proton beam therapy is in an early stage of clinical adoption. The new proposed ruling will enhance the possibility of establishing more proton therapy facilities, and/or allow for expansion of current proton centers in order to keep pace with the clinical demand by thousands of cancer patients across the country.

We appreciate the complexities of the hospital payment system and the challenges faced by CMS in developing the proposed rule. We are aware that CMS OPPS works closely with the hospital providers of proton therapy in order to understand and analyze data for payment classification purposes. That is reflected in the CY 2006 proposed rule that ensures the economic viability of both existing proton facilities and those in various stages of construction and development.

We are excited about the future of proton therapy for improving patient outcomes and quality-of-life. As Dr. James Cox, chairman of radiation oncology at the M.D. Anderson Cancer Center, said: *"Oncologists have long known that substituting proton beam radiation for X-rays now used to treat cancer patients would do less harm to normal tissues and organs and more damage to malignant growths. That means more cures."*

On behalf of the proton therapy industry, as well as the many thousands of cancer patients in the U.S. who seek proton radiation treatment, we thank you and your very capable CMS staff for the government's role in providing support for this leading-edge cancer therapy.

In conclusion, we agree with CMS's CY 2006 proposed payment rule for proton therapy and strongly support it being included in the final rule.

Thank you for your attention to this important matter. If you have any questions, I can be reached at 301-587-6100 or via email: lenarzt@proton-therapy.org.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'J. Arzt', with a stylized flourish at the end.

Leonard J. Arzt
Executive Director
NAPT

lenarzt@proton-therapy.org

Submitter : Alfred R. Smith, Ph.D.

Date: 09/16/2005

Organization : Particle Therapy Cooperative Group

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

8/7/05 Particle Therapy Cooperative Group Letter to Hon. Mark B. McClellan, M.D., Ph.D.; re Proton Beam Therapy Payment Classification.

CMS-1501-P-533-Attach-1.PDF

PARTICLE
THERAPY
CO-
OPERATIVE
GROUP

August 7, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 314 G
Washington, DC 20201

Re: Proton Beam Therapy Payment Classification

Dear Dr. McClellan:

In the Proposed Calendar Year (CY) 2006 Rule: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY'06 Payment Rates (CMS-1501-P), CMS proposed rule we note the following as it relates to proton therapy:

1. The proposed rule maintains separate classifications for simple, intermediate and complex proton therapies (CPT-4 codes 77520, 77522, 77523 and 77525, respectively).
2. CMS also proposes to move intermediate and complex proton therapies (CPT 77523 and 77525) from a New Technology APC (1511) into a clinical APC (0667).
3. Payment rates are proposed to be \$764.74 under APC 0664 for simple proton therapies (77520 and 77522) and \$914.92 under APC 0667 for intermediate and complex therapies (77523 and 77525).

We strongly support the classification and payment rates for simple, intermediate and complex proton therapies as proposed in the CMS CY 2006 OPPS rule. We urge CMS to make the proposed rule its final rule for CY 2006.

Maintaining separate APC rates for proton therapies of varied complexity is necessary to differentiate between resource demands of different treatment levels. The proposed rates more accurately reflect the significant capital demands associated with developing proton therapy centers and the high costs of operating them. The required equipment is significantly more expensive to purchase and maintain than standard radiation treatment equipment. A typical proton beam therapy center requires between \$70-\$125 million and more than three years of development. The implementation of the proposed rule will ensure that the Nation's premier cancer treatment centers have the ability to provide cancer patients with this successful treatment.

Also, it should be noted that Proton beam therapy is in an early stage of clinical adoption and therefore this technology has not been widely adopted. Therefore the number of claims data should be monitored carefully, as it is expected to be modest for the next 2-3 years.

Currently, over 46,000 cancer patients have been treated with protons around the world, including three institutions currently providing proton beam therapy in the United States. Positive clinical results from these facilities have stimulated worldwide interest in the clinical applications of proton therapy and consequently numerous facilities are in planning or construction phases. However, the number of sites establishing proton beam therapy centers has not kept pace with the clinical demand for the service. For those sites establishing centers, cost continues to be a major concern, which underscores the importance of maintaining adequate Medicare payment for the technology. It is critical that CMS OPPS continues to work with the providers of proton therapy to understand and analyze the data for classification and payment, as was clearly seen by the CY 2006 proposed rule, to ensure the economic viability of both existing facilities and those in various stages of construction and development.

Proton therapy is responsible for improving treatment outcomes and quality of life for cancer patients and, consequently, has raised our standard of care. Appropriate payment rates for proton beam therapy will ensure this leading-edge cancer therapy is available to those cancer patients who require more advanced treatments.

Thank you for your prompt attention to this critical issue.

Sincerely,

A handwritten signature in cursive script that reads "Alfred R. Smith".

Alfred R. Smith, Ph.D.

Chairman, Particle Therapy Cooperative Group

Submitter : Ms. Kathy Francisco
Organization : The Pinnacle Health Group, Inc
Category : Health Care Industry

Date: 09/16/2005


Issue Areas/Comments

GENERAL

GENERAL

Comments regarding the OPPS proposed rule regarding New Technology APC are attached.

CMS-1501-P-534-Attach-1.PDF


THE PINNACLE HEALTH GROUP
301 Oxford Valley Road, Suite 601B
Yardley, Pennsylvania 19067
215 369 9290 • 866 369 9290
www.thepinnaclehealthgroup.com

September 15, 2005

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Re: Proposed Changes to the OPPTS Payment System and 2006 Payment Rates - **New Technology APC**

Dear Dr. McClellan:

The Pinnacle Health Group, Inc. (Pinnacle) is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) in response to the July 25, 2005 *Federal Register* notice regarding the 2006 Hospital Outpatient Prospective Payment System (HOPPS) proposed rule.

The Pinnacle Health Group is an organization that supports hospitals and providers with coding and reimbursement information regarding new technology. On behalf of Pinnacle and the providers that Pinnacle supports we would like to thank CMS for the opportunity to make recommendations regarding the proposal to require the submission of a CPT code application as part of the New Technology APC criteria.

New Technology APCs

CMS proposes to require that an application for a code for a new technology service be submitted to the American Medical Association's (AMA) CPT Editorial Panel before CMS will accept a New Technology APC application for review. Furthermore, CMS is proposing that a copy of the submitted CPT application be submitted to CMS as a part of the application for a New Technology APC. CMS is also proposing to require a letter from the AMA acknowledging the CPT code application.

Pinnacle is concerned that the AMA CPT Editorial Panel may not be an appropriate forum for a federally mandated new technology decision. This requirement may add unnecessary delay of new technology to Medicare beneficiaries preventing rapid availability of new technology as intended by the MMA legislation.

The AMA CPT Editorial Panel is a private organization that is not subject to procedural protections that are required for public policy. AMA meetings are closed to the public and the basis for decisions are not available to the public, including hospitals and physicians. The AMA CPT Editorial Panel has no voting representatives from the medical technology industry and manufacturer community. Further, the panel is not subject to the protections of the Administrative Procedures Act, the Freedom of Information Act, or the Federal Advisory Committee Act.

The requirement of the submission to the AMA CPT Editorial Panel would require involvement of an organization that may not be accountable as are all other agencies that are subject to federal public policy decisions. This requirement may be an unlawful delegation of federal decision making to a private organization.

Category I codes are typically assigned to a procedure that has become an accepted standard of care thus defeating the purpose of adoption of new technology. If manufacturers are forced to apply for a CPT code before sufficient information is available, it is likely that the CPT Editorial Panel would assign a Category III (emerging technology) code that often results in a non-coverage decision by local Medicare carriers and fiscal intermediaries, and many commercial payers.

If the AMA CPT Editorial Panel were to agree to open its meetings to the public, place voting representatives of manufacturers on the decision making panel, and otherwise comply with the Administrative Procedures Act, Freedom of Information Act, and Federal Advisory Committee Act, then the proposed role of the AMA would more likely support continued rapid access of new technologies to Medicare patients. Until this time we recommend that CMS eliminate the proposed requirement that manufacturers submit a CPT application prior to submission of a New Technology APC application to CMS.

New technology continues to offer important treatment for Medicare patients. Appropriate and timely payment for new technologies permit Medicare beneficiary's full access to high quality care in the hospital outpatient setting just as other patients covered by private insurance.

We hope that CMS will take these issues under consideration during the development of the HOPPS Final Rule and eliminate the proposed requirement for a CPT application submission prior to the New Technology APC application.

Should CMS staff have additional questions, please contact me.

Sincerely,



Kathy A. Francisco
Principal, The Pinnacle Health Group, Inc.
kfran@thepinnaclehealthgroup.com

Submitter : Mrs. Erin Keyser
Organization : Woodcrest Healthcare, Inc.
Category : Health Care Provider/Association

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Bruce R. McMaken
Organization : M.D. Anderson Cancer Center
Category : Health Care Provider/Association

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

8/8/05 Bruce R. McMaken (Managing Director of The University of Texas, MD Anderson Cancer Center - Proton Therapy Center-Houston, Ltd., LLP) Letter to Hon. Mark B. McClellan, M.D., Ph.D.; re Proton Beam Therapy Payment Classification.

CMS-1501-P-536-Attach-1.PDF

THE UNIVERSITY OF TEXAS
**MD ANDERSON
CANCER CENTER**
PROTON THERAPY CENTER

August 8, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 314 G
Washington, DC 20201

Re: Proton Beam Therapy Payment Classification

Dear Dr. McClellan:

In the Proposed Calendar Year (CY) 2006 Rule (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2006 Payment Rates (CMS-1501-P)), we note the following proposed changes as they relate to proton beam therapy:

1. The proposed rule maintains separate classifications for simple, intermediate and complex proton therapies (CPT-4 codes 77520, 77522, 77523 and 77525, respectively).
2. CMS also proposes to move intermediate and complex proton therapies (CPT 77523 and 77525) from a New Technology APC (1511) into a clinical APC (0667).
3. Payment rates are proposed to be \$764.74 under APC 0664 for simple proton therapies (77520 and 77522) and \$914.92 under APC 0667 for intermediate and complex therapies (77523 and 77525).

We agree with the proposed rule for the following reasons:

1. Maintaining separate APC rates for proton therapies of varied complexity is necessary to differentiate between resource demands of different treatment levels.
2. The proposed rates more accurately reflect the significant capital demands associated with developing, and the high costs of operating, a proton therapy center.

We also note that proton therapy technology is in the early stages of diffusion and as such the number of claims data should be monitored carefully by CMS, as it is expected to be modest for the next two to three years, with an outlook to supporting patient access to proton beam therapy.

We strongly support the classification and payment rates for simple, intermediate and complex proton therapies as proposed in the CMS CY 2006 OPPTS rule. We urge CMS to make the proposed rule its final rule for CY 2006. This will ensure that the nation's premier cancer treatment centers have the ability to provide cancer patients with this successful treatment.

Currently, over 46,000 cancer patients have been treated with protons in many institutions around the world, including three institutions currently providing proton beam therapy in the United States. Positive clinical results from these facilities have stimulated worldwide interest in the clinical applications of proton therapy and consequently numerous facilities are in the planning or construction phases.

Proton beam therapy is in an early stage of clinical adoption. The required equipment is significantly more expensive to purchase and maintain than standard radiation treatment equipment. A typical proton beam therapy center requires approximately \$125 million and more than three years to develop. As a result, the number of sites establishing proton beam therapy centers has not kept pace with the clinical demand for the service. For those sites establishing centers, cost continues to be a major concern, which underscores the importance of maintaining adequate Medicare payment for the technology. It is critical that CMS OPPS continues to work with the providers of proton therapy to understand and analyze the data for classification and payment, as was clearly seen by the CY 2006 proposed rule, to ensure the economic viability of both existing facilities and those in various stages of development and construction.

Proton therapy is responsible for improving health outcomes, quality of life and our standard for cancer treatment. Appropriate payment rates for proton beam therapy will ensure this leading-edge cancer therapy is available to those we serve.

Thank you for your prompt attention to this critical issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Bruce R. McMaken", with a stylized flourish at the end.

Bruce R. McMaken
Managing Director
The Proton Therapy Center-Houston, Ltd., LLP

Submitter : Mrs. Erin Keyser
Organization : Woodcrest Healthcare, Inc.
Category : Health Care Provider/Association

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

Our agency Woodcrest Healthcare, Inc. is a freestanding community mental health center in Louisiana. We serve approximately 400 patients on an annual basis. We employ approximately 12 employees and contract workers in our community. We provide intensive psychiatric programs that are much needed by the patients in our community. Without our program, many of these patients would not receive and services or would be frequently hospitalized in psychiatric hospitals at the government's expense.

We are requesting that the proposed 15% cut for our program be stopped. The current payment rate, which represents a substantial cut from 2 years ago, is inadequate to cover the cost of our intensive program. This cut in our funding will result in the closure of our program that has been a fixture in our community for 8 years. Twelve people will be without work and 400 patients without services.

We have a 100% compliance rating and have never been denied payment for any services for any reason by CMS. We are independent from any hospital affiliation and do not share or spread costs with other departments.

Please consider halting the proposed cut to the Partial Hospitalization Program so drastically while many outpatient services are receiving increases in funding of up to 3.5%.

Our Community Mental Health Center services rural areas and is not funded by the state as a Medicaid service.

In light of the tragedy Hurricane Katrina wrought on our state it is unthinkable that such valuable mental health services be in jeopardy of losing funding. Our facility is currently active through volunteer work in the shelters and accepting patients displaced by the hurricane. At the very least, please consider leaving the rate at the 2005 level pending further review so we may continue to provide services to those in need.

Sincerely,

Erin Keyser
Billing Clerk

Submitter : Mrs. Rebecca Phillips
Organization : Woodcrest Healthcare, Inc.
Category : Nurse

Date: 09/16/2005

Issue Areas/Comments

GENERAL

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Sincerely, Rebecca Phillips, RN

Submitter : Mr. Joe Keyser
Organization : Woodcrest Healthcare, Inc.
Category : Health Care Provider/Association

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

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Submitter : Dr. Thomas DeLaney
Organization : Northeast Proton Center of Mass General Hospital
Category : Hospital

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1501-P-540-Attach-1.DOC

Draft #1

Submitted Electronically

September 16, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW.,
Washington, DC 20201

RE: CMS-1501-P, Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule.

Dear Dr. McClellan:

I am pleased to comment on the Proposed Rule for Medicare Prospective Payment System for Hospital Outpatient Services, 42 CFR Parts 419 and 485, July 25, 2005 Federal Register, on behalf of the Northeast Proton Therapy Center at Massachusetts General Hospital (Provider Number 220071), a founding member of Partners Health Care System.

Proton Beam Therapy

I agree that the CY 2004 claims data more accurately reflect the high capital and operating costs of proton beam facilities and, specifically, the cost of Level II (or "complex") proton beam radiation therapy. I support CMS' proposal to move CPT codes 77523 and 77525 from New Technology APC 1510 to clinical APC 0667. More importantly, the resulting national payment rate of \$914.92 for complex proton beam therapy will ensure access to this valuable therapy for Medicare and other patients as well.

Finally, I thank CMS for the reasoned and thoughtful transition of payment for proton beam therapy from New Technology APCs to proton beam specific clinical APCs. By maintaining payment for proton beam therapy in New Technology APCs until sufficient claims data was available to reflect the true cost of this therapy, CMS has both ensured continued access to this valuable therapy in existing proton therapy centers and, as importantly, supported the development of new centers throughout the country.

Sincerely,

Thomas DeLaney, MD
Medical Director
Northeast Proton Center

Submitter : Mr. Ben Keyser
Organization : Woodcrest Healthcare, Inc.
Category : Individual

Date: 09/16/2005

Issue Areas/Comments

GENERAL

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Sincerely,

Ben Keyser

Submitter : Mr. Glenn Hackbarth

Organization : MedPAC

Date: 09/16/2005

Category : Federal Government

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1501-P-542-Attach-1.DOC



Attachment #542

601 New Jersey Avenue, N.W. • Suite
9000
Washington, DC 20001
202-220-3700 • Fax: 202-220-3759
www.medpac.gov

Glenn M. Hackbarth, J.D., Chairman
Robert D. Reischauer, Ph.D., Vice

September 16, 2005

Mark McClellan, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: File code CMS-1501-P

Dear Dr. McClellan:

The Medicare Payment Advisory Commission (MedPAC) is pleased to submit comments on CMS's proposed rule entitled: *Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates*, Vol. 70, No. 141, pages 42673-43011 (July 25, 2005). We appreciate your staff's ongoing efforts to administer and improve the payment system for hospital outpatient services, particularly considering the agency's competing demands. We have comments on several of the issues addressed in the proposed rule, and where applicable we have included the captions specified in the rule.

As you know, the outpatient prospective payment system (OPPS) classifies services provided in outpatient departments into ambulatory payment classification (APC) groups. Each APC group has a relative weight, and the OPPS determines payments as the product of the relative weights and a conversion factor. The proposed rule documents changes in the composition of some APC groups and proposes changes to the relative weights based on analysis of claims and cost report data. It also discusses new policies required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), payment for drugs, parameters for outlier payments, and the movement of some services from new technology APCs to clinical APCs. Finally, the rule estimates the calendar year 2006 update to the conversion factor.

Our comments on the proposed rule center on three issues: the proposed adjustment of payments to sole community hospitals (SCHs) located in rural areas, payments for nonpass-through drugs, and discounted payments for certain imaging services when a hospital performs multiple imaging services in a single session.

Rural hospital adjustment

The MMA requires the Secretary to study whether rural hospitals incur greater costs than urban hospitals under the OPPS. If the Secretary finds a cost discrepancy, the MMA directs the Secretary to adjust OPPS payments to reflect the higher costs of rural hospitals.

The proposed rule includes an analysis by CMS of hospitals' outpatient costs per unit. Based on results of that analysis, CMS proposes to pay rural SCHs 6.6 percent above the standard APC payment rates.

CMS's analysis consists of a series of regressions that have the hospital as the unit of observation. The dependent variable in the first regression discussed in the proposed rule is hospitals' cost per unit from furnishing OPPS services. This regression has several explanatory variables, but the text in the proposed rule focuses on one: an indicator of whether a hospital is located in a rural area. Statistical tests show this variable has only marginal significance ($p\text{-value} = .058$), so CMS could have concluded that rural hospitals do not have higher costs than urban hospitals. Indeed, the proposed rule states that the "evidence is weak." CMS pursued the issue further, performing additional regressions that have hospitals' costs per unit as the dependent variable and that separate rural hospitals into several groups, including rural SCHs.

Results from these additional regressions show rural SCHs have statistically significant higher costs than urban hospitals. Based on this finding, CMS proposes to increase OPPS payments for rural SCHs.

We have three concerns about CMS's analysis:

- Model specification.
- Whether it is appropriate policy to focus payment adjustments on SCHs.
- The additional payments do not focus on assuring beneficiaries' access to care.

Model specification issues

We believe the regression model excluded some important variables that would have more completely identified whether a rural location has a significant effect on hospital costs. Conceptually, the kinds of variables that should be added reflect the financial pressures hospitals face and the structure of the hospitals' markets. The rationale for measures of financial pressure is that financial pressure can affect a hospital's incentive to hold down costs. The rationale for measures of market structure is that market structure can affect the competitive pressure on a hospital, which can affect their costs.

Focusing payment adjustments on SCHs may not be appropriate

Hospitals should not receive additional payments for relatively high costs if those high costs are due to inefficiency. It is plausible that the high costs experienced by SCHs are due to inefficiency because SCHs have special payment status under both the inpatient PPS (IPPS) and OPPS. Under the IPPS,

Mark McClellan
Administrator
Page 3

Medicare pays SCHs the greater of the IPPS amounts or amounts based on their historical costs updated to the current year. Under the OPDS, SCHs have had "hold harmless" status in 2004 and 2005, getting paid the greater of their PPS amounts or the amounts they would have been paid under the cost-based system that preceded the outpatient PPS. Under both PPSs, SCHs may be under less financial pressure than hospitals that are paid strictly their PPS amounts. CMS should investigate whether the higher costliness of SCHs is due to less financial pressure or to factors that are beyond their control.

Payment adjustments should focus on access to care

The central objective of any payment policy should be to ensure beneficiaries' access to care. Many SCHs are near other hospitals that have opened since the SCHs were granted their status. Others are near critical access hospitals, which are excluded when CMS considers whether a hospital meets the criteria for being an SCH. Because they are often near other hospitals, many SCHs are not essential to beneficiaries' access to care. Consequently, we believe payment adjustments should not focus on SCHs in rural areas.

We acknowledge that CMS is legally required to make this payment adjustment based on whether a hospital has a rural location. However, we believe a more appropriate policy would adjust payments to hospitals with relatively high costs for factors beyond the hospital's control, such as a relatively small scale of operation. Consequently, we encourage the Secretary to offer a legislative proposal to the Congress that would allow adjustments to OPDS payments to small-scale hospitals. Small scale could be measured by a hospital's volume of outpatient services provided. Of course, it is possible that a hospital has a small scale because of poor performance or because it is in a market with excess capacity. Therefore, payment adjustments should be directed only to hospitals that are at least a specified number of miles from other hospitals.

Payments for nonpass-through drugs

Our comments on payments for nonpass-through drugs include sections on payments for specified covered outpatient drugs (SCODs), overhead and handling costs for SCODs, and the issue of packaging drugs with related procedures for payment purposes.

Payment for specified covered outpatient drugs

The MMA directs Medicare to pay for SCODs provided in outpatient departments at the drugs' average acquisition costs beginning in 2006. But, if the data on acquisition costs are not available, the MMA allows Medicare to use alternative rates. The Government Accountability Office (GAO) has collected data on the purchase price of drugs that comprise most of the Medicare spending on SCODs, with the intent that Medicare could use them as acquisition costs. However, CMS has proposed to use 106 percent of manufacturers' average sales price (ASP), citing three problems with the purchase prices from GAO:

- The purchase prices do not fully account for manufacturer rebates or payments from group purchasing organizations.

- It would be difficult to update the purchase prices during 2006 and subsequent years.
- The purchase prices are from a less recent time period than the ASP data, and the purchase prices could have increased during the intervening period.

In cases where ASP data are not available, CMS will base payments on charge data from claims, adjusted to costs.

We acknowledge the problems presented by the purchase price data, and we recognize use of ASP data as a viable alternative. The ASPs are based on prices that manufacturers report to CMS every quarter and are net of discounts and rebates. However, a limitation of ASP data is that CMS derives ASPs from manufacturers' sales to all distribution channels—wholesalers, group purchasing organizations, hospitals and other providers such as physicians. Furthermore, reporting may not be consistent across manufacturers, and CMS may need to verify the accuracy of ASP data through confidential audits.

Although we support CMS's proposed use of ASPs, we are concerned about the proposal to pay most SCODs at a rate of 108 percent of ASP—106 percent of ASP for the drug and an additional 2 percent for handling costs. CMS's analysis in the proposed rule suggests that, for drugs covered by GAO's survey, hospitals' mean purchase price was equivalent to 103 percent of ASP. Given that average ASP values have declined in recent quarters and that GAO's data do not fully reflect rebates, we believe that the proposed payment rates may be too high.

Overhead and handling costs for specified covered outpatient drugs

The MMA directed MedPAC to submit a report to the Secretary on whether the payments for SCODs should have an adjustment to cover the costs of overhead and handling expenses. Our analysis suggests that these costs are not negligible. This is an important finding because of the MMA's requirement that CMS begin paying hospitals for SCODs on the basis of acquisition costs in 2006. Payments that equal the true acquisition cost of the drug do not compensate hospitals for overhead and handling costs.

We included the mandated study as part of our June 2005 Report to the Congress. We recommended that the Secretary establish separate, budget neutral payments to cover the costs hospitals incur for handling separately paid drugs, biologicals, and radiopharmaceuticals. We also recommended that the Secretary:

- define a set of handling-cost APCs that group drugs, biologicals, and radiopharmaceuticals based on attributes that affect handling costs;
- instruct hospitals to submit charges for these APCs; and
- base payment rates for the handling-cost APCs on submitted charges, adjusted to costs.

We are, in general, pleased that CMS's proposed method to pay for overhead and handling costs beginning in 2008 reflects our recommendations. The method would establish three HCPCS codes and three corresponding APC groups that are differentiated by characteristics affecting overhead and handling costs. Further, CMS proposes to instruct hospitals to submit charges for overhead costs to the appropriate HCPCS for each drug administration. CMS would collect these charges for two years (2006

and 2007) and consider basing payments for the three handling-cost APCs in 2008 on these charges adjusted to costs. This is similar to the method CMS uses to set payment rates for procedural APCs.

However, we are concerned about CMS's proposed method for paying overhead and handling costs in 2006, when the charge data necessary to set payments under the proposed method for 2008 are not yet available. For 2006, CMS proposes to pay hospitals 2 percent of ASP on each drug administration. We are concerned about the proportional nature of this method. We recognize that this is a difficult problem with no easy solution because of lack of data. But, CMS should consider another alternative because the proposed method ties reimbursement for handling costs directly to the acquisition cost of a drug, even though a high acquisition cost does not imply high handling costs. A potential consequence is that payments for the handling costs of a particular drug could differ sharply from the handling costs hospitals actually incur. In addition, CMS's proposed approach could become permanent rather than temporary. Finally, we are concerned that this method could result in higher prices paid by hospitals because it gives manufacturers an incentive to increase prices.

In place of the proposed method, we suggest that CMS estimate the total dollars that should be dedicated to paying handling costs—additional to the amount for acquisition costs—and determine how much of the total should be allocated to groups of drugs that are similar with respect to their handling costs. The following is an outline of a method CMS could use. Note that within this approach, hospitals would receive the same payment for handling costs for different SCODs within the same category of handling costs, no matter the drugs' acquisition costs.

- *Estimate pool of total handling costs.* CMS has proposed to pay handling costs for each SCOD in 2006 at a rate of 2 percent of the drug's ASP. Irrespective of the rate CMS chooses to use for acquisition costs (CMS has proposed 106 percent of ASP, but we speculate a lower rate may be justified), 2 percent of ASP is a viable basis for creating a pool of total handling costs for all SCODs. For each SCOD, CMS can calculate the product of an estimate of the drug's total volume and 2 percent of the drug's ASP. The total pool would be the sum of these products.
- *Collect SCODs into categories.* Collect the SCODs into the three handling-cost APCs discussed above.
- *Estimate handling costs for each category.* CMS can determine how much of the total pool should be allocated to each handling-cost APC using estimates of the relative handling costs and volume for the drugs in each APC. Our analysis of handling costs shows that handling costs per drug administration are about 15 times greater for drugs with the greatest handling costs relative to the drugs with the smallest handling costs. CMS could use this range of relative handling costs or handling cost data from other interested parties to determine how much to allocate to each APC. Within each APC, the handling-costs should be divided equally among drug administrations. Note that the range of relative costs we cited excludes radiopharmaceuticals, for which we have no data.

A final issue concerning drug handling costs is CMS's decision to collapse the seven handling-cost categories we developed in our June 2005 Report to the Congress into the three handling-cost APCs. We acknowledge that CMS's stated rationale is justifiable: Some drugs can fall into more than one of our categories, usually because different hospitals use different forms of the same drug. However, after

CMS collects the charge data necessary to set rates for the handling-cost APCs, we encourage CMS to explore whether it would be reasonable to expand the number of handling-cost APCs beyond three. We also encourage CMS to further research how to best construct categories of handling-cost APCs for radiopharmaceuticals, which are likely to require greater resources than drugs and biologicals

Packaging drugs with related services

Separate payments for the handling costs of SCODs will increase the degree of unpackaging in the OPPS. Under the OPPS, the unit of payment is the APC. Some APCs have extensive packaging, but every drug that costs at least \$50 per administration has its own APC as well as a separate payment for drug administration. We have long been concerned about the incentives created by the unpackaging that exists in the OPPS.

When a payment system packages some products and pays separately for others, providers have an incentive to use the products paid separately, if they are more profitable than packaged items. In an October 2003 Report to the Congress, we documented considerable increases in program spending on drugs that are used in dialysis treatment and billed separately from the composite rate. In the OPPS, providers have an incentive to use a higher-cost drug that is paid separately in place of a lower-cost drug that is packaged into the APC payment of the applicable service. If hospitals act on this incentive, it could raise beneficiaries' overall cost sharing, Part B premiums, and program spending.

In addition, setting payment rates for small packages is likely to be less accurate than setting rates for larger packages. Isolating a single input requires great precision in setting rates. With greater packaging, variations in charging practices are more likely to balance out, leading to payment rates that, on average, are closer to costs.

Finally, we believe incentives to use separately paid products may be exacerbated if CMS implements its proposal to apply budget neutrality for SCODs by reducing payment rates in all APCs except for the SCODs. For example, the financial incentive of using a SCOD instead of a packaged drug would be increased by the proposed method of budget neutrality. Moreover, it would create higher payments for hospitals that are relatively high users of SCODs and reduce payments for low users.

Discount for multiple diagnostic imaging procedures

Under the OPPS, hospitals receive full APC rates for each diagnostic imaging service on a claim, even though hospitals can save costs when they perform multiple services using the same imaging modality on contiguous body parts in the same session. We recommended in our March 2005 Report to the Congress that the Secretary improve coding edits that detect unpackaged diagnostic imaging services and reduce payments for multiple imaging services performed on contiguous body parts.

The proposed rule acknowledges that the OPPS currently discounts payments for multiple surgical procedures performed on the same patient in the same operative session. CMS believes a similar policy for diagnostic imaging services would be more appropriate than the current policy.

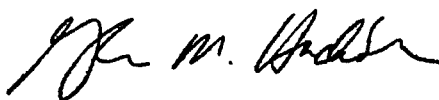
Mark McClellan
Administrator
Page 7

Table 32 of the proposed rule groups imaging services into 11 "families" by imaging modality and contiguous body area. Analysis by CMS shows that many claims report more than one imaging service within the same family provided on the same day. Further analysis shows that many costs incurred for an initial imaging service are not incurred in subsequent services. The proposed rule concludes that excluding the costs that are not incurred in subsequent services justifies a 50 percent reduction in payments for subsequent services provided in hospital outpatient departments. Therefore, CMS is proposing to reduce by 50 percent OPPS payments for multiple imaging services within the same family performed in the same session. Full payment would be made for the service with the highest APC rate, and the 50 percent discount would be applied to the APC rate for each additional service in the same family performed in the same session.

We support the direction that CMS proposes to take on this issue. However, CMS proposes to make these discounts budget neutral, preventing potential budgetary savings and lower cost sharing for beneficiaries. We acknowledge that CMS is legally required to make this budget neutral adjustment, but we encourage the Secretary to offer a legislative proposal to the Congress in order to capture the potential savings.

We appreciate your consideration of our comments. If you have any questions, feel free to contact me or Mark Miller, MedPAC's Executive Director, at (202) 220-3700.

Sincerely,



Glenn M. Hackbarth
Chairman

GMH/dz/wc

Submitter : Dr. Jill Firszt
Organization : Washington University School of Medicine
Category : Health Care Professional or Association

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

Centers for Medicare and Medicaid Services
US Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

File Code: CMS-1501-P
Issue Identifier: Device-dependent APCs

To Whom It May Concern:

Cochlear implantation has made a significant difference in the lives of recipients. Although individuals of all ages have successfully received cochlear implants, a great number of recipients are older adults who depend on Medicare for access to this life changing technology. Older adults who have been implanted have become more independent, more connected to their families and the world around them, and feel considerably safer when able to hear in their environment. Medical and insurance communities have accepted cochlear implantation as a standard treatment for hearing loss and comprehend the cost-effectiveness of this treatment. It is very concerning that there is a proposed 14% decrease in the reimbursement benefit for Medicare patients. The current level of reimbursement does not adequately cover the device and procedure for cochlear implantation. A reduction will lessen Medicare beneficiaries access to implantation and follow-up care for this procedure that improves the quality of life and ability to function independently and effectively in daily life for the vast majority of recipients.

I would request that CMS set the 2006 OPPS payment no lower than 100% of the 2005 payment rate plus the inflation and other update factors applied to all APCs. I'm sure you realize the impact of reimbursement on accessibility for Medicare beneficiaries. On behalf of the surgeons and clinicians at the Cochlear Implant Program of the Washington University School of Medicine, we appreciate your consideration of these comments.

Respectfully,

Jill B. Firszt, Ph.D.
Associate Professor
Department of Otolaryngology
Washington University School of Medicine
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FirsztJ@ent.wustl.edu

Submitter : Ms. Marilyn Halseth
Organization : Medtronic, Inc.
Category : Device Industry

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-544-Attach-1.DOC



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September 15, 2005

Mark McClellan, MD, PhD, Administrator
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-1501-P
7500 Security Boulevard
Baltimore, MD 21244-1850

ELECTRONICALLY SUBMITTED

**RE: Hospital Outpatient Prospective Payment System Proposed Rule [CMS-1501-P]
Update for Calendar Year 2006**

Dear Dr. McClellan:

Medtronic, Inc. is one of the world's leading medical technology companies, specializing in implantables and interventional therapies that alleviate pain, restore health and extend life. Medtronic Neurological appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule on Changes to the Medicare Outpatient Prospective Payment System and Payment Rates for CY 2006, published in the *Federal Register* on July 25, 2005. Our comments that follow are related to **Pass-Through Device Categories**.

Medtronic fully supports Medicare's proposal to create an additional category for devices that meet all of the criteria required to establish a new category for pass-through payment in instances where an existing or previously existing category descriptor does not appropriately describe the new type of device. We also support CMS' application of the two tests to determine eligibility and we urge CMS to finalize this proposal.

Furthermore, Medtronic has a pending pass through application for which we believe this proposal would apply. A pass through application was made February, 28, 2005 for Restore™, Medtronic's rechargeable implantable neurostimulator for the treatment of chronic, intractable pain. As you are aware, this technology was approved, effective October 1, 2006, for a New Technology Add-On Payment under the Hospital Inpatient Prospective Payment System. It is our belief that this technology meets the two part test under the following rationale.

1. It is not similar to devices whose cost is currently reflected in outpatient claims data.

Rechargeable neurostimulators, Radio Frequency (RF) neurostimulators and non-rechargeable neurostimulators are distinctly different technologies. Radio Frequency neurostimulators require an external power source that must be worn continuously for therapy to be delivered. This power source is not rechargeable. Studies have demonstrated lower patient compliance with this type of device due to skin breakdown, irritation and other issues.

Rechargeable neurostimulators have an internal power source that is recharged once every 3-6 weeks using an external recharger that the patient wears for a short period of time. Patients are able to receive the therapy continuously without concern for battery life or skin irritation and breakdown. Non-rechargeable neurostimulators also have an internal power source, however it is not rechargeable. Upon depletion of the battery, the patient must undergo replacement surgery to continue receiving the therapy. Non-rechargeable neurostimulators also provide continuous therapy.

The earliest available implantable rechargeable neurostimulator was the Precision™ Spinal Cord Stimulation System, manufactured by Advanced Bionics Corporation, which received FDA approval on April 2004. Precision™ Spinal Cord Stimulation System became available for commercial distribution on a limited basis in June 2004. All other currently available rechargeable neurostimulators, Restore™, Genesis®, and Eon™, were not commercially distributed until 2005. Based on the fact that Precision™ was commercially available on a very limited basis for the last six months of 2004, implantable rechargeable neurostimulators are not reflected in the current outpatient claims data, which captures dates of service from January 1, 2004 through December 31, 2004.

2. Provides substantial clinical improvement.

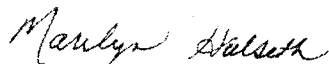
Rechargeable neurostimulators represent a significant clinical improvement over existing technology. Rechargeable technology provides more treatment options for those patients requiring high energy stimulation. Prior to the approval of rechargeable neurostimulators, patients with high energy needs often underwent frequent neurostimulator replacement or they were unable to experience the full benefit of neurostimulation due to battery conservation. Rechargeable technology provides for a reduction in surgeries related to neurostimulator replacement caused by battery depletion.

Additionally, physicians are able to use two 16-electrode leads instead of the 8-electrode leads used in older neurostimulators. By using leads with more electrodes, physicians can place the leads so that more coverage is provided to the spinal nerves. This also provides for the option to reprogram the neurostimulator if a lead migrates after implantation, thereby avoiding an invasive surgery for lead revision.

Medtronic device registry data has demonstrated that 34% of patients aged 54 and older, who receive non-rechargeable devices, require replacement surgery within 10 years of implant. More than half of those patients have high energy needs that deplete the battery within the first three years. As previously stated, rechargeable technology provides for the avoidance of these battery replacement surgeries. Additionally, it has been demonstrated that patient compliance is vastly improved with rechargeable technology.

In closing we appreciate your consideration of our comments and respectfully request that CMS consider the information provided in this letter as well as information previously submitted, to qualify rechargeable neurostimulation technology for the establishment of a new device category eligible for pass-through payment in the hospital outpatient setting. Questions or requests for additional information should be directed to Marilyn Halseth at (763) 505-0277.

Respectfully,

A handwritten signature in cursive script that reads "Marilyn Halseth".

Marilyn Halseth
Reimbursement Manager
Medtronic Neurological
710 Medtronic Parkway NE
Minneapolis, MN 55423